Supreme Court, U.S.
FILED
07-186 AUG 13 2007
OFFICE OF THE CLERK

No.

In The
Supreme Court of the United States

CROSS MEDICAL PRODUCTS, INC.,
PETITIONER,

v.

MEDTRONIC SOFAMOR DANEK, INC.
AND MEDTRONIC SOFAMOR DANEK USA, INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

J. SCOTT BALLENGER
Counsel of Record
LATHAM & WATKINS LLP
555 11TH STREET, N.W.
SUITE 1000
WASHINGTON, DC 20004
(202) 637-2200

BRUCE D. KUYPER
MARK A. FINKELSTEIN
MARK D. KACHNER
LATHAM & WATKINS LLP
650 TOWN CENTER DRIVE
20TH FLOOR
COSTA MESA, CA 92626
(714) 540-1235

QUESTION PRESENTED

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), this Court established a "tangential relation" test for rebutting the presumption of prosecution history estoppel. The Federal Circuit has now significantly altered this Court's "tangential relation" test, rendering it practically impossible to meet. This has upset the balance that this Court set between the doctrine of equivalents and prosecution history estoppel. This has also significantly reduced the value of potentially millions of patents. Should the Federal Circuit's material alteration of this Court's important precedent be permitted?

RULE 29.6 STATEMENT

Petitioner Cross Medical Products, Inc. is a wholly-owned subsidiary of Interpore Spine Ltd. which, in turn, is a wholly-owned subsidiary of EBI Holdings, Inc. which, in turn, is a wholly-owned subsidiary of Electro-Biology, Inc. which, in turn, is a wholly-owned subsidiary of Biomet Investment Corp. which, in turn, is a wholly-owned subsidiary of Biomet, Inc. which is a publicly traded corporation. The Blackstone Group is a publicly held corporation that owns more than 10% of Biomet, Inc.'s stock.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

RULE 29.6 STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES iv

OPINIONS BELOW 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 1

STATEMENT OF THE CASE 1

REASONS FOR GRANTING THE WRIT 10

I. UNDER THIS COURT'S PRECEDENTS, A PATENTEE CAN REBUT THE PRESUMPTION OF PROSECUTION HISTORY ESTOPPEL WHERE THE REASON FOR AN AMENDMENT BEARS NO MORE THAN A TANGENTIAL RELATION TO THE EQUIVALENT IN QUESTION 12

II. THE FEDERAL CIRCUIT HAS EVISCERATED THIS COURT'S "TANGENTIAL RELATION" TEST FOR REBUTTING THE PRESUMPTION OF PROSECUTION HISTORY ESTOPPEL 15

III. THIS CASE RAISES AN ISSUE OF GREAT NATIONAL IMPORTANCE 19

CONCLUSION 21

TABLE OF AUTHORITIES

Page(s)

CASES

Amgen, Inc. v. Hoechst Marion Roussel, Inc.,
457 F.3d 1293 (Fed. Cir. 2006),
cert. denied, 127 S. Ct. 2270 (2007) 10, 18, 20

Amgen, Inc. v. Hoechst Marion Roussel, Inc.,
287 F. Supp. 2d 126 (D. Mass. 2003),
affirmed in part, vacated in part,
457 F.3d 1293 (Fed. Cir. 2007),
cert. denied, 127 S. Ct. 2270 (2007) 19

Burns v. Meyer,
100 U.S. 671 (1879) 13

Chimie v. PPG Industries Inc.,
402 F.3d 1371 (Fed. Cir. 2005) 16

Exhibit Supply Co. v. Ace Patents Corp.,
315 U.S. 126 (1942) 13

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
535 U.S. 722 (2002) ..... *passim*

Graver Tank & Manufacturing Co. v.
Linde Air Products Co.,
339 U.S. 605 (1950) 12, 13, 20

Keystone Driller Co. v. Northwest Engineering Corp.,
294 U.S. 42 (1935) 13

Kinzenbaw v. Deere & Co.,
741 F.2d 386 (Fed. Cir. 1984) 13

Lucent Technologies, Inc. v. Gateway, Inc.,
No. 02cv2060-B (CAB), 2007 U.S. Dist. LEXIS 16682
(S.D. Cal. Mar. 6, 2007) 20

TABLE OF AUTHORITIES—Continued

Page(s)

O'Reilly v. Morse,
56 U.S. (15 How.) 62 (1854) 12

Sanitary Refrigerator Co. v. Winters,
280 U.S. 30 (1929) 12

Tyler v. Boston,
74 U.S. (7 Wall.) 327 (1868) 14

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17 (1997) ..... *passim*

Winans v. Denmead,
56 U.S. (15 How.) 330 (1853) 13

CONSTITUTIONAL PROVISIONS AND STATUTES

U.S. Const. Article 1, Section 8, Clause 8 1

35 U.S.C. § 112 ..... 5, 8, 15

35 U.S.C. § 271(a) 1

LEGISLATIVE HISTORY

H.R. Rep. No. 97-312 (1981) 21

OTHER AUTHORITY

3 Donald S. Chisum, *Chisum on Patents*
§ 7.03 (2005) 5

TABLE OF AUTHORITIES—Continued

Page(s)

John R. Allison and Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 Stan. L. Rev. 955, 972 (2007) 14

Ana Cristina Almeida Müller, *Protecting Biotechnological Inventions in Brazil and Abroad: Draft, Scope and Interpretation of Claims*, 13 Alb. L.J. Sci. & Tech 145, 170 (2002) 19

Honorable Pauline Newman, *The Federal Circuit: Judicial Stability or Judicial Activism?*, 42 Am. U. L. Rev. 683, 687 (1993) 21

OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit (Pet. App. 1a–22a) is reported at 480 F.3d 1335. The opinion of the district court (Pet. App. 39a–58a) is reported as an unpublished decision at 2005 WL 5239258 (C.D. Cal. Apr. 11, 2005). Prior decisions of the U.S. Court of Appeals for the Federal Circuit (Pet. App. 59a–110a) and the district court (Pet. App. 23a–30a) and (Pet. App. 31a–38a) are reported, respectively, at 424 F.3d 1293 (Fed. Cir. 2005) as well as at 2004 WL 5234564 (C.D. Cal. May 18, 2004) and 2004 WL 5234565 (C.D. Cal. Aug. 19, 2004).

JURISDICTION

The Federal Circuit denied a petition for rehearing or rehearing en banc on May 15, 2007. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article 1, Section 8, Clause 8 of the United States Constitution provides:

The Congress shall have the power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." 35 U.S.C. § 271(a).

STATEMENT OF THE CASE

The district court found that respondents Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA's (collectively, "Medtronic") spinal implant screws infringe claim 5 of petitioner Cross Medical Products, Inc.'s ("Cross") U.S. Patent No. 5,474,555 (the "'555 Patent"). After that adverse ruling, Medtronic made an insubstantial

and non-functional design change to its screws. But the district court found that Medtronic's redesigned screws still infringed claim 5 of the '555 Patent under the doctrine of equivalents.

On appeal to the Federal Circuit, Medtronic did not challenge the district court's finding that its spinal implant screws infringed claim 5 under the doctrine of equivalents. Instead, Medtronic argued that Cross was estopped from relying on that doctrine because of changes that were made to the patent claim while the patent was being prosecuted before the Patent Office.

The Federal Circuit ruled that a narrowing amendment was made to claim 5 during the prosecution of the '555 Patent, establishing a presumption of prosecution history estoppel under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). In *Festo*, this Court held that the presumption of prosecution history estoppel may be rebutted by showing, *inter alia*, that "the *rationale underlying the amendment* [bears] no more than a tangential relation to the equivalent in question." *Id.* at 740. (emphasis added).

This "tangential relation" test can be illustrated by the following example. Suppose that a wooden box is the subject of a patent claim, and that the Patent Office requires the patentee to amend the claim to distinguish a prior patent for a wooden box that can be disassembled and put back together. Suppose further that the claim is amended to specify that the wooden box is held together with glue. If the equivalent product in question is a wooden box held together with rubber cement, the different adhesive in the equivalent product would be unrelated to the *reason* for the claim amendment—to distinguish the claimed invention from wooden boxes that can be disassembled—since the equivalent product also cannot be disassembled. The prosecution history should not be an obstacle to proving infringement under the doctrine of equivalents in such circumstances. Prosecution history estoppel should bar the

patent owner from suing the manufacturer of a box *that can be disassembled*, since the unpatentability of such boxes was the reason for the amendment. But if someone makes a box that is permanently fastened together in a way that is only trivially different from the manner specified in the patent, the doctrine of equivalents should still apply.

The Federal Circuit, however, has reformulated this Court's "tangential relation" test in a manner that deprives it of all meaning and significance. Instead of asking whether the equivalent in question bears no more than a tangential relationship to the *reason* for the amendment, the Federal Circuit now just asks whether "the accused equivalent ... *relates to the amendment*." Pet. App. 12a. (emphasis added). In other words, the Federal Circuit would ask only whether the rubber cement in the example above bears a more than tangential relationship to glue—which, properly understood, ought to be irrelevant.

The Federal Circuit's new test cannot be reconciled with this Court's holding in *Festo*, and radically alters the balance between the doctrine of equivalents and prosecution history estoppel. Under the Federal Circuit's test, an infringer can rely on prosecution history estoppel to avoid liability under the doctrine of equivalents simply by making trivial changes to the product that are related to the *result* of an amendment that was made in the Patent Office—even if those changes have nothing to do with the *reason* for the amendment or the scope of appropriate patentability. In such circumstances, the allegedly infringing device will *always* bear more than a tangential relationship to the amendment that was made in the Patent Office. Thus, the rebuttable presumption of prosecution history estoppel has now become virtually irrebuttable, despite a long line of precedent from this Court reaffirming the importance of the doctrine of equivalents for ensuring appropriate incentives for innovation.

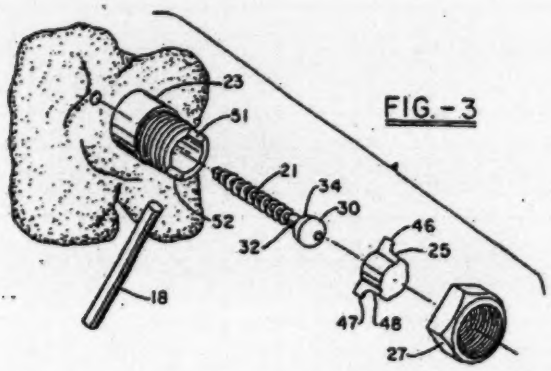
If the Federal Circuit's new test for rebutting prosecution history estoppel is allowed to stand, significant patent rights to numerous patent holders will have been destroyed, as this

new test has essentially resurrected the pre-*Festo* "complete bar" against the doctrine of equivalents upon amendment of a claim.

Prosecution History of U.S. Patent No. 5,474,555

The patent at issue in this case describes an orthopedic surgical implant used to stabilize and align the bones of a patient's spine. *See* Pet. App. 60a. The claimed apparatus includes a bone screw fixed to the spine, an elongated stabilizer rod designed to join anchors implanted in adjacent vertebrae, and a means to secure the stabilizing rod to the anchor.

As shown in a figure taken from the patent and reproduced in the court of appeals' opinion itself (shown below), a preferred embodiment of the '555 Patent includes a cap (25) between the compression nut (27) and the rod (18). In this preferred embodiment, it is this cap, rather than the nut, that contacts the rod.



In the original patent application filed with the Patent Office, all claims recited the use of a cap between the nut and the rod. Non-Confidential Joint Appendix, at A2284–87, *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed. Cir. Dec. 12, 2005). During the prosecution of the '555 Patent, however, claims were added

that did *not* recite the use of a cap. *Id.* at A2314–18. Claim 5 (originally claim 15) was one such claim added during prosecution. *Id.*

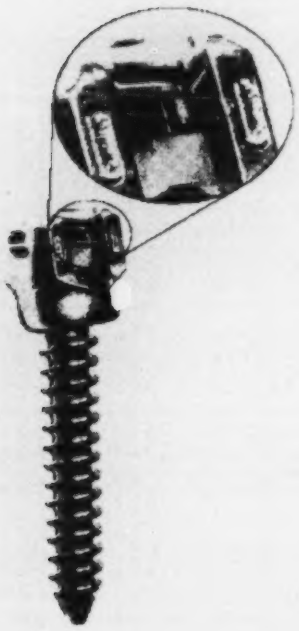
Once new claims were proposed that eliminated the cap as an element, the examiner considered, among other things, whether those claims were "enabled" under 35 U.S.C. § 112, such that the patent claims sufficiently described the invention to enable a person skilled in the relevant art to make and use the invention. 3 Donald S. Chisum, *Chisum on Patents* § 7.03 (2005). The examiner rejected claim 5, as originally drafted, for lack of enablement, taking the position that the claim failed "to provide an enabling description of the embodiment of the action device excluding the cap/cap means." Non-Confidential Joint Appendix, at A2327, *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed. Cir. Dec. 12, 2005). To overcome this rejection, the claim was amended to add the recitation at the heart of this dispute, which recitation required that the threads of the anchor seat extend toward the bone interface "to a depth below the diameter of the rod." *See* Pet. App. 12a. This additional language provided a way for the nut to be tightened directly against the stabilization rod itself without the use of an intermediate cap, providing adequate stabilization for the rod and thereby enabling those skilled in the art to make and use the claimed invention. Thus, the rationale for this amendment was to ensure functionality of the device without an intermediate cap component.

Proceedings In the District Court

Like Cross, Medtronic is a medical technology company. In early 2003, Cross, as the assignee of the '555 Patent, brought a patent infringement lawsuit against Medtronic alleging, *inter alia*, that Medtronic infringed claim 5 of the '555 Patent through its manufacture and sale of certain spinal implant screws. On May 18, 2004, the district court granted Cross' motion for partial summary judgment, concluding that Medtronic indeed infringed claim 5 of the '555 Patent. *See* Pet. App. 29a. After the district court concluded that

claim 5 was not invalid, it granted Cross' motion for a permanent injunction as to Medtronic's infringing spinal screws.

Following the district court's rulings, Medtronic made slight and non-functional changes to its polyaxial spinal screws that the district court had determined infringed claim 5 of the '555 Patent. Cross moved for summary judgment that these redesigned screws also infringed claim 5 of the '555 patent. The district court examined Medtronic's altered screws, and recognized that the "only difference between the old and new screw designs is that the new design replaces the threads below the top of the rod with a groove or 'undercut.'" Pet. App. 44a. In other words, all that Medtronic did was remove a few threads at the bottom of the anchor seat. This undercut does not engage or interfere with any surface of the corresponding set screw. The redesign was merely Medtronic's attempt to avoid the literal terms of the claim language stating that the threads of the anchor seat extend toward the bone interface "to a depth below the diameter of the rod." *See* Pet. App. 5a. Below is a photograph of one of Medtronic's redesigned spinal screws with an exploded view showing the undercut:



Like the prior infringing design, Medtronic's redesign still ensured that the set screw could be tightened directly against the stabilization rod.

The district court first examined literal infringement, and concluded that Medtronic's redesigned screws did not literally infringe claim 5. Pet. App. 45a–46a.

Next, the district court considered whether Cross could rely on the doctrine of equivalents to show that Medtronic's redesigned screws infringe claim 5 of the '555 Patent. The district court reasoned that because Cross amended claim 5 during prosecution to add the "thread depth" language, and because the amendment was made for purposes of patentability, prosecution history estoppel was presumed. Pet. App. 46a.

Consistent with this Court's decision in *Festo*, the district court then concluded that Cross adequately rebutted the presumption of prosecution history estoppel by showing that the rationale underlying the amendment was no more than tangentially related to Medtronic's new screw design. The

district court agreed with Cross that the amendment—requiring that the threads of the anchor seat extend toward the bone interface "to a depth below the diameter of the rod"—was in response to the examiner's enablement rejection under 35 U.S.C. § 112, and was added to adequately enable the claimed device such that the securing means (the nut) could secure the rod without the use of a cap. Pet. App. 47a. The district court further recognized that the amendment was not designed to overcome prior art using an undercut rather than threads, and that the reason for the amendment was completely unrelated to changes that Medtronic made to its design. *Id.* ("[T]he rationale behind the amendment was to adequately describe and enable a device, under § 112, in which the securing means could secure the rod without the use of a cap. The applicant was not attempting to overcome prior art..."). Accordingly, the district court concluded that under this Court's decision in *Festo*, Cross could rely on the doctrine of equivalents to prove that Medtronic's redesigned screws infringed claim 5 of the '555 Patent.

The district court then determined that Medtronic's redesigned screws infringed claim 5 of the '555 Patent under the doctrine of equivalents. Pet. App. 51a. To establish infringement under the doctrine of equivalents, the patentee must establish that the accused device "contain[s] elements identical or equivalent to each claimed element." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39–40 (1997). And for mechanical devices, this test is generally satisfied by showing that the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the patented invention. *Id.* Medtronic's corporate designee testified that Medtronic's old screw and new screw "work[] the same," and that the undercut "doesn't change the functionality at all. The thread continues down until it can push against the rod in either case." Pet. App. 49a. Based on the foregoing, the district court concluded that Medtronic's redesigned screws

infringe claim 5 of the '555 Patent. *See* Pet. App. 48a–49a. ("Medtronic's new screw design, containing a complete thread and an undercut, performs substantially the same function (enabling the securing means to reach a depth below the top of the rod) in substantially the same way (by cooperating with the threads of the securing means) to achieve substantially the same result (to capture the rod between the securing means and the channel)."). Accordingly, the district court granted Cross' motion for partial summary judgment of infringement.

Proceedings on Appeal

On appeal, Medtronic argued that Cross should have been estopped from relying on the doctrine of equivalents. Medtronic did not challenge the district court's ruling that, if Cross is not estopped, the redesigned spinal screws would infringe under that doctrine.[1]

The Federal Circuit agreed with the district court, and with Cross, that "the patentee narrowed claim 5 to address a § 112 rejection," not to overcome a prior art rejection. Pet. App. 9a. Although the court of appeals recognized that this was the *reason* for the amendment, and did not disagree with the district court's finding that Medtronic's alteration was unrelated to that reason, it nonetheless held that prosecution history estoppel applies because "the accused equivalent which does *not* include threads extending 'to a depth below the top of the stabilizer' and correspondingly does *not* capture this aspect of the invention relates to the amendment." *Id.* at 12a. (emphasis in original). In other words, the Federal Circuit held that prosecution history estoppel must apply because Medtronic's alteration bears more than a tangential relation to the amendment itself (as opposed to the *reason* for the amendment). In doing so, the

---

[1] While this appeal was pending the Federal Circuit issued a ruling in a prior pending appeal, 424 F.3d 1293, finding certain unresolved factual issues regarding infringement of Medtronic's screws, and validity of claim 5, that require a trial.

Federal Circuit reaffirmed its earlier statement in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1310 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2270 (2007), that "the tangential relation criterion for overcoming the *Festo* presumption is *very narrow*." Pet. App. 10a. (emphasis added).

REASONS FOR GRANTING THE WRIT

The Federal Circuit has abandoned the test for rebutting the presumption of prosecution history estoppel that this Court unanimously announced just five years ago in *Festo*, and substituted its own entirely different analysis that severely disrupts the balance between prosecution history estoppel and the doctrine of equivalents. The Federal Circuit's new test cannot be reconciled with this Court's precedent; it significantly alters the legal landscape of patent law and severely skews the incentives necessary to promote scientific progress.

The doctrine of equivalents protects patent owners against infringers who make only insubstantial changes to an invention. But without limits, the doctrine of equivalents would encroach upon the definitional and public-notice function of patent claims. Prosecution history estoppel then developed as a natural limit on the doctrine of equivalents, because if a party was forced to abandon a particular claim during the prosecution process, it should not be able to resurrect the abandoned material indirectly via the doctrine of equivalents. On the other hand, if the *reason* that a claim was amended has nothing to do with the difference in the accused equivalent product, then prosecution history should not preclude the patentee from relying on the doctrine of equivalents to prove infringement. Otherwise, a potential infringer could avoid the patent by engineering its product to incorporate some tangential or irrelevant feature related to the claim amendment—even if that feature had nothing to do with the *reason* the patentee amended the claim.

In formulating and applying the prosecution history estoppel doctrine, therefore, this Court has tried to strike a

careful balance between ensuring that patent owners have recourse against infringers, and that patent owners do not abuse the doctrine of equivalents to revive claims that they were properly forced to disclaim. As part of this balance, this Court has examined "the reasoning behind the Patent Office's insistence upon a change in the claims" and "the manner in which the amendment addressed and avoided the objection," to determine whether prosecution history should limit the scope of the doctrine of equivalents. *Warner-Jenkinson Co.*, 520 U.S. at 31–33 & n.7. A narrowing amendment made for purposes of patentability thus erects only a rebuttable presumption of prosecution history estoppel. *Festo Corp.*, 535 U.S. at 740–41 (overturning the Federal Circuit's holding that prosecution history erects a complete bar against the doctrine of equivalents).

Most recently, in *Festo*, this Court recognized that although "the doctrine of equivalents renders the scope of patents less certain," this is "the price of ensuring the appropriate incentives for innovation." 535 U.S. at 732. This Court held that prosecution history estoppel does not bar the doctrine of equivalents "for aspects of the invention that have only a peripheral relation to the *reason* the amendment was submitted." *Id.* at 738 (emphasis added).

In *Amgen* and now in this case, the Federal Circuit has abandoned the balance that this Court struck in *Festo* in favor of a new test for rebutting the presumption of prosecution history estoppel that ignores the *reason* for the narrowing amendment and instead focuses on the end *result* of the amendment. This new test jettisons diligent examination of the rationale for a narrowing amendment, replacing the inquiry with a glance at the end result of that amendment. And because prosecution history estoppel is typically invoked only when features of the alleged equivalent are intertwined with the amended subject matter, it is virtually inevitable that the result of the amendment will relate, in some way, to the alleged equivalent. The Federal Circuit's new analysis thus makes the presumption of

prosecution history estoppel essentially unrebuttable—which rule this Court specifically rejected in *Festo*.

The Federal Circuit's adoption of a novel test for rebutting the presumption of prosecution history estoppel has been closely watched by the intellectual property community, and a decision in this case will have a significant impact on the scope of all patent rights. The Federal Circuit has substantially weakened those rights and this case is an opportunity for the Court to re-establish the test that it espoused only a few years ago. Certiorari is warranted.

I. UNDER THIS COURT'S PRECEDENTS, A PATENTEE CAN REBUT THE PRESUMPTION OF PROSECUTION HISTORY ESTOPPEL WHERE THE REASON FOR AN AMENDMENT BEARS NO MORE THAN A TANGENTIAL RELATION TO THE EQUIVALENT IN QUESTION

The doctrine of equivalents is judicial recognition that a patent's scope extends beyond the claim's literal terms to protect an inconsequential variation to a patentable invention. Since no patentee can possibly anticipate all of the insubstantial alterations future infringers might attempt in order to evade the patent, the doctrine of equivalents is essential to prevent patent rights from becoming an empty promise. *See Warner-Jenkinson Co.*, 520 U.S. at 17 (confirming continued vitality of doctrine of equivalents); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) (doctrine of equivalents prevents conversion of patent protection into "a hollow and useless thing"); *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929) ("A close copy which seeks to use the same substance of the invention, and, although showing some change in form and position, uses substantially the same devices, performing precisely the same offices with no change in principle, constitutes an infringement."); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 123 (1854) (well-settled that a mere change in the form of the machinery, or an alteration in some of its

unessential parts, will not avoid an infringement finding); *Winans v. Denmead*, 56 U.S. (15 How.) 330, 344 (1853) (first apparent recognition of doctrine of equivalents). Without the doctrine of equivalents, an "unscrupulous copyist" would be encouraged "to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim," rendering patent rights "hollow and useless." *Graver Tank & Mfg. Co.*, 339 U.S. at 607. The doctrine of equivalents also extends patent protection to "unanticipated equivalents" found in technology after a patent has issued. *See Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 389 (Fed. Cir. 1984).

The doctrine of equivalents, however, has limits to prevent patents from losing their definitional and public-notice functions. *See Warner-Jenkinson Co.*, 520 U.S. at 29 (noting that too broad an application of the doctrine of equivalents may conflict with definitional and public-notice function of claims); *Graver Tank & Mfg. Co.*, 339 U.S. at 614 (Black, J., dissenting); *Burns v. Meyer*, 100 U.S. 671, 672 (1880) (warning courts not to enlarge patent claims beyond the fair interpretation of its terms). One such limit is the objectively apparent reasons underlying narrowing amendments that were made for purposes of patentability. The rationale for this limitation is to prevent a patent applicant from recapturing subject matter that was intentionally disclaimed when the scope of patent rights was being negotiated with the patent examiner. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136 (1942) (doctrine of equivalents cannot be relied on to recapture claims which the patentee surrendered by amendment); *Keystone Driller Co. v. Nw. Eng'r Corp.*, 294 U.S. 42, 48 (1935) ("patentee is estopped to read the granted claim as the equivalent of those which were rejected" and narrowed by amendment). But because an amendment related to patentability may include features that are unrelated to the reason why the claim was amended, focusing on the

rationale for the amendment is the only way to ensure that the prosecution history estoppel doctrine serves the purposes for which it was designed. *See Warner-Jenkinson Co.*, 520 U.S. at 33.

Acknowledging the importance of the doctrine of equivalents, this Court reasoned that "[a]fter amendment, as before, language remains an imperfect fit for invention," and ruled that "[t]he amendment does not show that the inventor suddenly had more foresight in the drafting of claims than an inventor whose application was granted without amendments having been submitted." *Festo*, 535 U.S. at 738. Further, this Court recognized that "there is no more reason for holding the patentee to the literal terms of an amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent." *Id.* This is particularly true for mechanical device inventions, which are more prone than patents in other technical fields to rely on the doctrine of equivalents. *See Tyler v. Boston*, 74 U.S. (7 Wall.) 327, 330 (1869) (declining to extend doctrine of equivalents with equal force outside scope of mechanical inventions); *see also* John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 Stan. L. Rev. 955, 973 (2007) (expressing a belief that the doctrine of equivalents was designed with mechanical inventions in mind).

In *Warner-Jenkinson*, this Court instructed the Federal Circuit to "consider whether *reasons* for that portion of the amendment were offered or not and whether further opportunity to establish such *reasons* would be proper," to assess whether that *reason* is sufficient to avoid estoppel. 520 U.S. at 34. (emphasis added). This Court unequivocally rejected the notion that an amendment made during patent prosecution categorically surrenders anything beyond the claim's literal terms. *See id.*

More recently, in *Festo*, this Court struck a balance between prosecution history estoppel and the doctrine of equivalents when it ruled that, if a patentee makes a

narrowing amendment during prosecution, there is only a *rebuttable presumption* of estoppel. *Festo Corp.*, 535 U.S. at 740. (the presumption of estoppel is not a "complete bar by another name"). This Court held that a patentee could overcome the presumption that prosecution history estoppel bars the doctrine of equivalents "where the amendment cannot reasonably be viewed as surrendering a particular equivalent." *Id.* The Court enumerated instances in which prosecution history estoppel would not apply following a narrowing amendment, including where "the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question." *Id.* at 740.

The Court also stated that prosecution history estoppel would not apply to a narrowing amendment when the equivalent was "unforeseeable at the time of the application," or where there was "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo Corp.*, 535 U.S. at 740–41. But Cross is not aware of any case where the Federal Circuit applied either the foreseeability test or the rarely invoked residual criterion to rebut prosecution history estoppel. Therefore, the tangential relationship test is the most important *Festo* criterion for maintaining balance between the doctrine of equivalents and prosecution history estoppel.

II. THE FEDERAL CIRCUIT HAS EVISCERATED THIS COURT'S "TANGENTIAL RELATION" TEST FOR REBUTTING THE PRESUMPTION OF PROSECUTION HISTORY ESTOPPEL

In this case, the Federal Circuit did acknowledge the *reason* for the narrowing amendment, which (as the district court correctly held) self-evidently had nothing to do with the modification by which Medtronic seeks to avoid the doctrine of equivalents. Pet. App. 12a ("the prosecution history explains that the thread depth language was added to capture the manner in which the stabilizer aspect of the invention operated and thereby overcome the 35 U.S.C.

§ 112 rejections."). But as it has in another recent case, the Federal Circuit ignored the *reason* for the amendment when determining whether prosecution history estoppel applies. The Federal Circuit instead simply inquired whether "the accused equivalent ... *relates* to the amendment." *Id.* (emphasis added). Although the thread-depth language in claim 5 concededly was not necessary to avoid prior art or any other problem requiring a narrowing amendment, but instead was simply one means (among many possible means) of enabling the invention to function, the Federal Circuit in effect held that the thread-depth feature has become an absolute requirement for infringement of claim 5—such that no other implementation of the invention could infringe the claim under the doctrine of equivalents.

That analysis is completely inconsistent with the tangential relation test that this Court set forth in *Festo*, 535 U.S. at 740–41. The cost of this new test is a significant reduction in the scope of the doctrine of equivalents, in areas where this doctrine has traditionally been of great value.

Medtronic's undercut is completely unrelated to how the rod operates. The set screw in Medtronic's device makes direct contact with and secures the stabilizer rod with or without the undercut; the undercut merely provides another, equivalent way, to achieve the same direct compression without the use of a cap component. The district court determined that the undercut "doesn't change the functionality at all. The thread continues down until it can push against the rod in either case." Pet. App. 49a. While the Federal Circuit agreed with the district court that the amendment was made to overcome an enablement rejection, the Federal Circuit reached a contrary conclusion as to estoppel because it departed from this Court's test for rebutting the presumption of prosecution history estoppel.

The Federal Circuit supported its holding in this case by observing that "the prosecution history of the '555 patent shows a narrowing amendment that also 'contains the equivalent in question.'" Pet. App. 12a (quoting *Chimie v.*

PPG Indus. Inc., 402 F.3d 1371, 1383 (Fed. Cir. 2005)). But it will always be the case that an amendment will "contain the equivalent in question" where a competitor makes an inconsequential variation to a patentable invention to avoid literal infringement. Now, no matter the *reason* for an amendment, under the Federal Circuit's new test, a competitor can rely on the *result* of an amendment during patent prosecution, make a related insubstantial change, and avoid infringement both literally and also under the doctrine of equivalents.

The Federal Circuit's new test is contrary to both the letter and the spirit of this Court's decision in *Festo* that *the rationale* underlying the amendment--not the amendment itself—must bear no more than a tangential relation to the equivalent in question. *Festo*, 535 U.S. at 740. This Court's decision in *Festo* clearly envisions that there will be situations in which the result of the amendment is directly related to the claimed equivalent, but the reason for the amendment is no more than tangentially related to the equivalent design. By abandoning that critical distinction between the *scope* of an amendment and the *reasons* for that amendment, the Federal Circuit has created a test for prosecution history estoppel that is effectively insurmountable—thereby contravening this Court's mandate that "[t]his presumption is not, then, just the complete bar by another name." *Id.* at 741.

In his concurrence, Judge Rader seemingly would have the "tangential relation" criterion completely read out of the test for rebutting presumed prosecution history estoppel. *See* Pet. App. 17a–22a (Rader, J. concurring). Judge Rader states that "the tangential rebuttal principle exacerbates the policy deficiencies of the doctrine of equivalents ... and undermines principles of public notice." *Id.* at 19a. But this Court acknowledged this balance when it stated that, while "the doctrine of equivalents renders the scope of patents less certain," this is "the price of ensuring the appropriate incentives for innovation." *Festo Corp.*, 535 U.S. at 732.

The balance that this Court established, and which the Federal Circuit has taken away, must be restored.

This is the second time that the Federal Circuit has applied this same incorrect version of the "tangential relation" test. The first time was in *Amgen*, 457 F.3d at 1293. In *Amgen,* the patent at issue covered an anemia drug known as recombinant erythropoietin ("EPO"). EPO is a protein naturally occurring in humans; the patent covered a method of producing EPO in commercial quantities. The Federal Circuit relied on a narrowing amendment that *resulted* in a claim limited to EPO having the "complete 166-amino acid sequence." In holding that Amgen was estopped from invoking the doctrine of equivalents against a 165-amino acid variation—with no functional difference from the claimed 166-amino acid version found in the patent—the court of appeals brushed aside significant evidence that the actual *reason* for the amendment was "to avoid a double patenting rejection" in light of a related patent claiming non-naturally occurring EPO that did not specify the length of the amino acid sequence. *Amgen*, 457 F.3d at 1314–15. Thus the *reason* for the amendment was merely to distinguish the application from the prior art. The patentee could have chosen from a number of grounds to distinguish its invention from the prior art and chose to amend the application by specifying the precise length of the amino acid sequence. The court explicitly acknowledged that the limitation added in the preliminary amendment "may have been central to overcoming a double patenting rejection," yet it still relied solely on the *result* of the amendment (specifying the length of the amino acid sequence) to conclude that the amendment was not "merely tangential to the alleged 165-amino acid equivalent." *Id.* at 1315.

The Federal Circuit in *Amgen* also added an inappropriate gloss on the governing standard by stating that this Court's decision in *Festo* recognized only "narrow ways" to rebut the presumption of prosecution history estoppel. *Id.* at 1310. This statement was also repeated in

this case. *See* Pet. App. 10a. Yet nowhere did this Court ever state, or even imply, that the "tangential relation" criterion for rebutting the prosecution history estoppel presumption should be "narrowly" applied.

Prior to appeal, the district court in *Amgen* applied this Court's *Festo* test and astutely ruled that "the correct inquiry is not whether the amendment itself narrows the scope of a claim in a way that affects the equivalent in question. If this were the test, it would be an impassable one—the only reason why the dispute arises is because the equivalent is related to the amendment and thereby affected." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 150 (D. Mass. 2003), *aff'd in part, vacated in part*, 457 F.3d 1293 (Fed. Cir. 2007), *cert. denied*, 127 S. Ct. 2270 (2007).

The Federal Circuit's most recent decisions regarding prosecution history estoppel fail to follow this Court's decision in *Festo*, effectively overruling it by reinstating a non-rebuttable rule of prosecution history estoppel.

III. THIS CASE RAISES AN ISSUE OF GREAT NATIONAL IMPORTANCE

Prosecution history estoppel polices the critically important boundary between the doctrine of equivalents and the need to confine a patent to its claims. This boundary serves to define the scope of patent rights, and is frequently the subject of litigation. Because the Federal Circuit's new test is virtually insurmountable, prosecution history has been effectively restored to a "complete bar" against the doctrine of equivalents and, according to one academic, may destroy the value of well over a million patents. *See* Ana Cristina Almeida Müller, *Protecting Biotechnological Inventions in Brazil and Abroad: Draft, Scope and Interpretation of Claims*, 13 Alb. L.J. Sci. & Tech 145, 170 (2002). As this Court has recognized, preservation of the doctrine of equivalents is "respectful of the real practice before the PTO." *Festo*, 535 U.S. at 738.

The Federal Circuit's new test is binding on district courts and will certainly greatly affect decisions across the

country. At least one district court has already applied the Federal Circuit's incorrect recitation of the tangentially related test.

In *Lucent Technologies, Inc. v. Gateway, Inc.*, the district court determined that narrowing amendments were made during prosecution for reasons of patentability and therefore presumed prosecution history estoppel. No. 02cv2060-B (CAB), 2007 U.S. Dist. LEXIS 16682, at *19–21 (S.D. Cal. Mar. 6, 2007). In determining whether the patentee could rebut this presumption, the court, citing *Amgen*, 457 F.3d at 1313, asked "how related (verses [sic.] how peripheral) the amendment (and the accused equivalent) is to the other amendments made to distinguish over the prior art." *Lucent Techs., Inc.* at *27. The court did not inquire into the reason for the amendment. *Id.* at *29. Instead, the court determined that the amendment "[was] directly related to the same subject matter" as the accused equivalent, and concluded that the tangential criterion was not satisfied. *Id.* Like the Federal Circuit in *Amgen* and *Cross*, the district court in *Lucent* applied a test that did not rely on the *reason* for the narrowing amendment made during prosecution.

The Federal Circuit's new test also ignores the crucial role of the doctrine of equivalents in preventing an "unscrupulous copyist" from making unimportant and insubstantial changes to a patent. *See Graver Tank & Mfg. Co.*, 339 U.S. at 607. By nearly eliminating a patent owner's ability to invoke the doctrine of equivalents after amendment, the Federal Circuit has provided a means for companies to copy important inventions without liability. Companies can simply review the prosecution history of patents they would like to infringe, find a narrowing amendment, and find an insignificant and non-functional way to avoid literal infringement that is related in some way to the amended claim. Under the Federal Circuit's new test for rebutting prosecution history estoppel, liability will be avoided, even where the reason for an amendment had nothing to do with the insignificant modification. The

Federal Circuit's dangerous new precedent thus upsets the balance between prosecution history and the doctrine of equivalents.

The goal of granting the Federal Circuit exclusive jurisdiction in patent cases was to promote national uniformity in patent law. *See* H.R. Rep. No. 97-312, at 20-22 (1981) (creation of Federal Circuit intended to reduce forum shopping and promote certainty within the patent system). The countervailing vice of that uniformity is that a clear error of law articulated by the Federal Circuit becomes operative nationwide, and without meaningful checks from other circuit courts of appeals. The Honorable Pauline Newman, *The Federal Circuit: Judicial Stability or Judicial Activism?*, 42 Am. U. L. Rev. 683, 687 (1993). The Federal Circuit's new standard for prosecution history estoppel dramatically upsets the balance of patent law, is inconsistent with this Court's decisions, and will define the scope of patent rights nationwide until this Court intervenes to correct it. Given the importance of the doctrine of equivalents to the preservation of patent rights, it is vital that this Court put the law back onto a more sensible path.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

J. SCOTT BALLENGER
Counsel of Record
LATHAM & WATKINS LLP
555 11TH STREET, N.W.
SUITE 1000
WASHINGTON, DC 20004
(202) 637-2200

BRUCE D. KUYPER
MARK A. FINKELSTEIN
MARK D. KACHNER
LATHAM & WATKINS LLP
650 TOWN CENTER DRIVE
20TH FLOOR
COSTA MESA, CA 92626
(714) 540-1235

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CROSS MEDICAL PRODUCTS, INC., Plaintiff-Appellee,

v.

MEDTRONIC SOFAMOR DANEK, INC. and Medtronic Sofamor Danek USA, Inc., Defendants-Appellants.

No. 05-1415.

March 20, 2007.

Rehearing and Rehearing En Banc Denied May 15, 2007.

---

480 F.3d 1335

Before RADER, SCHALL, and PROST, Circuit Judges.

Opinion of the court filed PER CURIAM. Concurring opinion filed by RADER, Circuit Judge.

PER CURIAM.

This case is the second appeal to this court in a patent litigation between Cross Medical Products, Inc. (Cross Medical) and Medtronic Sofamor Danek, Inc. (Medtronic). Cross Medical accuses Medtronic's polyaxial screws of infringing U.S. Patent No. 5,474,555 (the '555 patent). In the prior appeal, this court set aside a permanent injunction issued by the United States District Court for the Central District of California and reversed the summary judgment of infringement and validity of claim 5 of the '555 patent in

favor of Cross Medical. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed.Cir.2005) (*First Appeal*). In this appeal, the district court issued another permanent injunction after Medtronic redesigned its polyaxial screws in an attempt to avoid the '555 patent. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, SA CV 03-110-GLT, slip op. at 2 (C.D. Cal. April 8, 2005) (*Trial Court Opinion*). The court determined that claim 5 of the '555 patent was infringed under the doctrine of equivalents by Medtronic's redesigned screws, but that claim 7 of the '555 patent was not infringed by either the original or redesigned screws. *Id.*, slip op. at 14, 20. Notably, the district court did not have the benefit of this court's opinion in the *First Appeal* before issuing the second permanent injunction.

Because Medtronic's redesigned polyaxial screws do not infringe the asserted claims literally or under the doctrine of equivalents, this court reverses the grant of summary judgment of infringement of claim 5. On the redesigned screws, the district court should grant Medtronic's motion for summary judgment of non-infringement. The remaining issues, which involve the validity of claim 7 and infringement of this claim by Medtronic's original polyaxial screws require reconsideration in light of this court's prior opinion in the *First Appeal*. Accordingly, this court reverses-in-part and vacates-in-part the district court's findings on the remaining issues and remands.

I

This litigation began on February 4, 2003, when Cross Medical sued Medtronic for infringement of the '555 patent. Medtronic denied infringement and counterclaimed seeking a declaration of non-infringement and invalidity. On September 28, 2004, the district court issued a permanent injunction after granting Cross Medical's motions for partial summary judgment on validity and infringement of claim 5. Medtronic immediately filed an appeal with this court

despite ongoing proceedings at the district court. *First Appeal*, 424 F.3d at 1299.

While the first appeal was pending, Medtronic redesigned its polyaxial screws in an attempt to avoid infringement of claim 5. In response, Cross Medical asserted that the redesigned screws still infringe claim 5 and that Medtronic's original and redesigned screws infringe claim 7.

On the claim 5 issue, the district court found that Medtronic's redesigned screws infringe under the doctrine of equivalents. *Trial Court Opinion*, slip op. at 22. In reaching this finding, the district court determined that a narrowing amendment to claim 5 during prosecution was only "tangentially related" to the accused equivalent and thus not subject to an estoppel under *Festo*. Id., slip op. at 8-11; *see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed.Cir.2003) (*en banc*). The district court also found that none of the accused screws (original or redesigned) infringe claim 7. *Trial Court Opinion*, slip op. at 14-20, but upheld the validity of this claim in the face of similar challenges Medtronic had previously raised with respect to claim 5. *Trial Court Opinion*, slip op. at 20-22. Having concluded Medtronic's redesigned screws infringe claim 5, the district issued a second permanent injunction. Medtronic filed a second appeal with this court, which is the basis for the present appeal.

After Medtronic submitted its initial brief in this appeal, this court issued its opinion overturning the first permanent injunction. *See First Appeal*, 424 F.3d 1293. In the *First Appeal*, which involved claim 5 and Medtronic's original polyaxial bone screws, this court (1) affirmed the district court's construction of three limitations; (2) modified its construction of two limitations; (3) reversed its grant of summary judgment on infringement; (4) affirmed its grant of summary judgment on validity for indefiniteness and anticipation; and (5) reversed its grant of summary judgment

on validity for obviousness due to factual issues on the motivation to combine various references. *Id.* at 1297.

This appeal overlaps considerably with the issues in the *First Appeal*. Because the *First Appeal* remanded several issues common to both injunctions, the parties agree that the second permanent injunction cannot stand. However, the parties dispute what issues, if any, remain for decision in this second appeal. Cross Medical asserts that the only issues remaining are: (1) whether the redesigned Medtronic screw meets the "thread-depth" limitation of claim 5 literally or under the doctrine of equivalents; and (2) whether the district court's grant of summary judgment of non-infringement of claim 7 conflicts with this court's findings with respect to claim 5 in the *First Appeal*. Br. of Pl. Appellee, 3, *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed.Cir.2006) (*Appellee Brief*). Of these two issues, Medtronic argues that only the claim 5 issue is properly before the court. According to Medtronic, this court lacks jurisdiction to entertain the claim 7 issue because Cross Medical did not file a cross-appeal to challenge the district court's adverse holdings with respect to this claim. Reply Br. of Defs.-Appellants, 16-24, *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed.Cir.2006) (*Reply Brief*).

II

With that backdrop, this court turns first to the claim 5 issue. The district court granted Cross Medical a summary judgment that Medtronic's redesigned screws infringe. "This court reviews the district court's grant or denial of summary judgment under the law of the regional circuit." *MicroStrategy, Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1349 (Fed.Cir.2005) (citation omitted). The United States Court of Appeals for the Ninth Circuit reviews a grant of summary judgment without deference. *Leonel v. Am. Airlines, Inc.*, 400 F.3d 702, 708 (9th Cir.2005). Thus, "[i]n the context of summary judgment, this court reviews de novo

the district court's determination that there is no genuine issue as to any material fact regarding infringement." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326 (Fed.Cir.2006) (citing *MEMC Elec. Materials v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1373 (Fed.Cir.2005)).

Having already concluded that Medtronic's original screws infringe claim 5, the district court examined the redesigned screws for appropriation of the "thread depth" limitation as well as the rest of the claimed features. *See Trial Court Opinion*, slip op. at 6. Specifically, claim 5 reads:

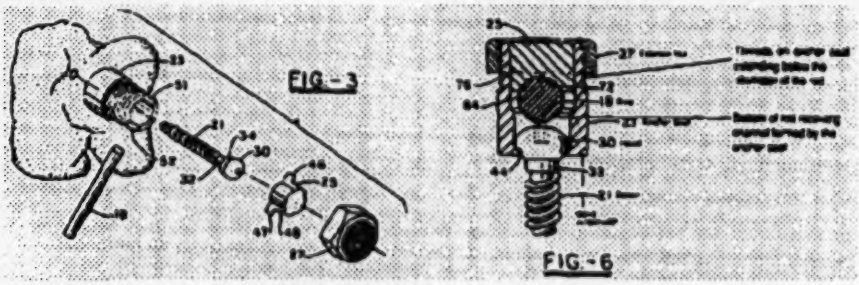
> 5. A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:
>
> at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis, said anchors each comprising anchoring means which secure said anchors to said bone segment and an anchor seat means which has a lower bone interface operatively joined to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod; and
>
> securing means which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, *said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod* when it is in the rod receiving channel, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive

BEST AVAILABLE COPY

> forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8 ll. 33-57 (emphasis added). On literal infringement, the district court determined that Medtronic's redesign, which "replaces the threads below the top of the rod with a groove or 'undercut[,]'" lacks thread forms and thus "does not literally meet the limitation requiring 'threads' extending below the top of the rod." *Trial Court Opinion*, slip op. at 6-7.

As described in the specification, the thread depth limitation corresponds to the anchor seat 23 shown in Figures 3 and 6 of the '555 patent and the threading thereon:



The embodiments of Figures 3 and 6 show that the threads on the anchor seat 23 extend to a depth below the top surface of the rod 18 as claimed. Notably, this thread depth requirement was not in the '555 patent's original application. Rather, the originally filed claim simply called for a "seat means including a vertical axis and first threads" without any particular limitation about the extent of the threading. The Examiner rejected this original claim, however, for lack of antecedent basis and lack of support in the specification. (35 U.S.C. § 112, ¶¶ 1-2), for obviousness type double patenting over U.S. Patent No. 5,360,431, and for anticipation (35 U.S.C. § 102(b)) over U.S. Patent No. 4,805,602 (the 602 patent). In response, the Applicant amended the claim (originally numbered as claim 15) to recite:

> 15. (Amended) A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:
>
> ....
>
> securing means which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, said seat means including a vertical axis and first threads *which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel*, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

In the same filing, the Applicant also amended the specification to address the 35 U.S.C. § 112, ¶ 1 rejection and submitted a terminal disclaimer to address the double patenting rejection. Thereafter, the Patent Office allowed the claim.

Medtronic apparently focused on this prosecution history in attempting to design around claim 5. Specifically, as noted by the district court, Medtronic altered its original screw design to terminate the corresponding threads at a position *above* the rod diameter. The district court agreed with Medtronic that the redesign took their screws outside the literal scope of claim 5. *Trial Court Opinion*, slip op. at 7 ("The new design does not literally meet the limitation requiring 'threads' extending below the top of the rod."). However, the district court still found the screws infringe claim 5 under the doctrine of equivalents' function-way-result test. Id., slip op. at 11. In so holding, the district court

rejected Medtronic's argument that a *Festo* presumption barred application of the doctrine of equivalents:

> [T]he rationale behind the amendment [to claim 5] was to adequately describe and enable a device, under § 112, in which the securing means could secure the rod without the use of a cap. The applicant was not attempting to overcome prior art using an undercut, and the amendment did not relate to an undercut. Therefore, the rationale was no more than tangentially related to Medtronic's new screw design, in which threads extend part of the way toward the rod and an undercut extends to a depth below the top of the rod. Medtronic's new screw design is "beyond a fair interpretation of what was surrendered." *Festo*, 535 U.S. at 738, 122 S.Ct. 1831. *Trial Court Opinion,* slip op. at 10.

Trial Court Opinion, slip op. at 10. Medtronic challenges this reasoning and seeks summary judgment of non-infringement both under literal infringement and equivalents.

A. Literal Infringement

Turning first to literal infringement, Medtronic replaced the threading that extends below the diameter of the rod in its original screws with an undercut that does not engage any surface on the corresponding set screw. Cross Medical characterizes this undercut as effectively a thread because it constitutes the root of an incomplete thread. The district court considered this argument by Cross Medical and properly rejected it as stretching the meaning of "thread" too far. *Id.*, slip op. at 7 (rejecting Cross Medical's argument that "the undercut is an 'effective thread,' which the parties agree is a complete thread, plus portions of an incomplete thread that are fully formed at the root but not at the crest"). As explained by the district court, the undercut in Medtronic's screws is not a thread because no thread forms in the undercut to join the flanks of adjacent thread forms above the diameter of the rod. *Id.* Simply because the

undercut appears adjacent to a thread form does not convert that independent structure into a thread. Thus, the district court properly found that this limitation only can be satisfied, if at all, under the doctrine of equivalents.

B. Infringement by Equivalents

Prosecution history estoppel prevents a patentee from recapturing under the doctrine of equivalents subject matter surrendered during prosecution to obtain a patent. *See Festo*, 344 F.3d at 1365 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002) (*Festo VIII*)). Indeed, by surrendering subject matter, a narrowing amendment classically invokes the doctrine. In this case, the patentee narrowed claim 5 to address a § 112 rejection. An amendment made to comply with § 112 may give rise to estoppel. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1142 (Fed.Cir.2004) (*en banc*) ("[I]f a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112.") Although these circumstances create a presumption of estoppel under *Festo*, the patentee may still rebut that presumption. *Rhodia Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1382 (Fed.Cir.2005) ("The patentee may rebut that presumption by showing that the alleged equivalent was unforeseeable at the time the amendment was made, that the alleged equivalent was tangential to the purpose of the amendment, or that there was some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.") In this case, the district court determined that Cross Medical successfully overcame the *Festo* presumption by demonstrating that the

amendment bore no more than a tangential relationship to the equivalent.

On appeal, Cross Medical argues that the amendment to claim 5 was tangential or, in the alternative, that it was unforeseeable. This court reaffirms the principle that the tangential relation criterion for overcoming the *Festo* presumption is very narrow and finds that neither the narrow tangential rebuttal principle nor the foreseeability principle applies to this case.

As discussed in the *Festo* opinion, the tangentially related

> criterion requires a patentee to demonstrate that "the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question." *Festo VIII*, 535 U.S. at 740, 122 S.Ct. 1831, 152 L.Ed.2d 944. In other words, this criterion asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.

Festo, 344 F.3d at 1369 (quoting *Festo VIII*, 535 U.S. at 740, 122 S.Ct. 1831). The *Festo* court further stated: "Although we cannot anticipate the instances of mere tangentialness that may arise, we can say that an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." *Id.* Finally, the court observed that the inquiry into whether a patentee can rebut the *Festo* presumption under the "tangential" criterion focuses on the patentee's objectively apparent reason for the narrowing amendment and that the reason "should be discernible from the prosecution history of record, if the public notice function of a patent and its prosecution history is to have significance." *Id.*

Cross Medical's reliance on *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed.Cir.2004), is misplaced. In *Insituform*, the invention claimed a method of impregnating an inner layer of resin with a limitation that

specified the number and location of vacuum cups used in the method. *See Id.*, 385 F.3d at 1368-69 (citing U.S. Patent No. 4,366,012, claims 1-4). The applicant added the number and location limitations to overcome prior art that disclosed a single vacuum source at the end of the tube opposite the resin source. *Id.* at 1369. In asserting a bar on the application of the doctrine of equivalents, the defendants argued that this narrowing amendment "necessarily gave up coverage of any process in which the vacuum was created at multiple vacuum sources," as in the accused processes. *Id.* at 1370. This court found instead that the prosecution history showed that "the reason for the amendment was to overcome the prior art teaching creation of a single source vacuum at the far end of the liner." *Id.* In other words, an amendment distinguishing prior art based on *where* the vacuum source was located was only tangentially related to an equivalent directed at the *number* of vacuum sources. *See Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed.Cir.2005) (explaining that, in *Insituform*, "the reason for the amendment and the alleged equivalent involved different aspects of the invention-the location of the vacuum source relative to the resin versus the number of vacuum cups" (citing *Insituform*, 385 F.3d at 1370)).

In *Insituform*, this court stated that in an analysis to determine if an amendment is tangential, "[t]he question we must address is 'whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.'" 385 F.3d at 1370 (citing *Festo*, 344 F.3d at 1365). Accordingly, this court has addressed the relationship between the narrowing amendment and the equivalent in broad terms: "[A]n amendment made to avoid prior art that contains the equivalent in question is not tangential." *Rhodia Chimie*, 402 F.3d at 1383. This court also added, "[i]t does not follow, however, that equivalents not within the prior art must be tangential to the amendment." *Id.* Indeed, in *Rhodia*, this court ultimately

determined that the applicant "surrendered the range between its original claim and its amended claim and is therefore estopped from asserting ... the doctrine of equivalents." *Id.*

In this case, the prosecution history of the '555 patent shows a narrowing amendment that also "contains the equivalent in question." *Id.* The '555 patent Applicant explained to the Examiner that:

> the claims have ... been amended to define the anchor seat means having a channel and threads which cooperate with the securing means (i.e., the nut) so as to capture the stabilizer between the channel and the securing means since the ancor [sic] seat *threads extend toward the channel to a depth below the top of the stabilizer* when it is in the channel.

In other words, the prosecution history explains that the thread depth limitation was added to capture the manner in which the stabilizer aspect of the invention operated and thereby overcome the 35 U.S.C. § 112 rejections. Thus, the accused equivalent, which does not include threads extending "to a depth below the top of the stabilizer" and correspondingly does not capture this aspect of the invention relates to the amendment as shown even by the applicant's own statements. For this reason, the district court erred in reliance on the tangential rebuttal principle to avoid the doctrine of equivalents.

As an alternative, Cross Medical argues that the alleged equivalent was unforeseeable at the time of the amendment and thus the *Festo* presumption could be overcome with this rebuttal criterion. *See Festo*, 344 F.3d at 1365 (commenting that the presumption can also be overcome "by demonstrating that 'the equivalent [would] have been unforeseeable at the time of the [amendment]'" (quoting *Festo VIII*, 535 U.S. at 740-41, 122 S.Ct. 1831)). To the contrary, the evidence of record clearly demonstrates that the use of an undercut or recess, the alleged equivalent here, is

an old and well known fundamental of basic machining that was entirely foreseeable at the time of the amendment to one of ordinary skill in the art. *See, e.g.*, John R. Walker, *Machining Fundamentals, Fundamentals Basic to Industry*, at 185-86 (1981); U.S. Patent No. 5,129,900; U.S. Patent No. 5,190,543.

Even Cross Medical implicitly recognized this fact in its literal infringement argument. Namely, Cross Medical suggests that an "undercut" was known in the art to serve effectively as a thread. Of course, this contention also means that the ordinary artisan would have considered an undercut as a foreseeable way to operate the invention—meaning that the patent drafter had an obligation therefore to include an undercut within the scope of the claim if it intended the invention to extend to that foreseeable means of using the invention. *See Ranbaxy Pharm., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1241 (Fed.Cir.2003) (holding that if an allegedly infringing product was readily known by those of skill in the art to be equivalent to the claim limitation, "it would have been foreseeable to literally include [it] in the claim"); *see also Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355, 1359-60 (Fed.Cir.2003). Thus, the district court properly did not rely on unforeseeability as a rebuttal of the presumption of surrender in the narrowing amendment. *See Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1361 (Fed.Cir.2005) (citing *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed.Cir.1997)) ("[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] foreseeable alteration of its claimed structure."); *Smithkline Beecham Corp. v. Excel Pharm., Inc.*, 356 F.3d 1357, 1363 (Fed.Cir.2004) ("Usually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro® in relation to fasteners) or technology that was not known in the

relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable."); *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1353 (Fed.Cir.2004) (same).

C. Summary

For the foregoing reasons, this court concludes that Cross Medical cannot satisfy its burden of overcoming the *Festo* presumption on either the tangentially related criterion or the foreseeability criterion. Because Medtronic's redesigned screws do not literally infringe claim 5 and *Festo* bars capturing these screws under the doctrine of equivalents, the district court should have granted summary judgment of non-infringement in favor of Medtronic under both literal infringement and infringement by equivalents regarding this claim.

III

Turning next to the claim 7 infringement issue, the district court found that "Medtronic's old and new screw designs do not infringe the limitation of claim 7 requiring an 'anchor seat including external threads.'" *Trial Court Opinion*, slip op. at 17. As discussed below, the district court properly granted summary judgment of non-infringement of claim 7 on Medtronic's redesigned screws. However, because the district court's grant of summary judgment of non-infringement of claim 7 on Medtronic's original screws is called into question by this court's treatment of similar limitations in claim 5 in the *First Appeal*, this court vacates this aspect of the district court's summary judgment grant and remands for further proceedings consistent with the *First Appeal*.

A. Redesigned Screws

While not identical to claim 5, claim 7 contains similar limitations beyond the scope of Medtronic's redesigned screws. Specifically, claim 7 reads:

7. A device for the stabilization of one or more bone segments, comprising:

at least two anchors and a rod having a diameter, said anchors each comprising screw means, an anchor seat, and a nut, said *anchor seat including external threads* and a channel to receive said rod and having a rod contacting surface in the bottom of the channel and *said threads extending toward the rod contacting surface to a thread run-out, the distance between the rod contacting surface and the thread run-out being less than the diameter of the rod*; and said nut including top and bottom surfaces and a relatively constant diameter through *bore having threads which mate with the threads of the anchor seat* and said nut being exterior to said rod and tightening down toward the rod whereby said bottom surface applies to compressive force to said rod.

'555 patent, col.8 l.62-col. 10 l.4 (emphasis added). Notably, the district court concluded Medtronic's redesigned screws do not meet the limitation "said threads extending toward the rod contacting surface to a thread run-out, the distance between the rod contacting surface and the thread run-out being less than the diameter of the rod" for reasons similar to the literal infringement analysis of claim 5. *Trial Court Opinion*, slip op. at 19. Cross Medical argues that this finding was in error because, as argued with respect to claim 5, the undercut in Medtronic's product purportedly constitutes an "effective thread." Having already rejected this argument, this court affirms this aspect of the district court's grant of summary judgment in favor of Medtronic.

B. Original Screws

Turning next to the original screws, the parties dispute whether this court has jurisdiction to entertain this issue at all. Medtronic argues that a cross-appeal is a necessary predicate to considering this issue and, in its absence, this

court lacks jurisdiction. Cross Medical argues that this court may consider the issue as an "alternative" basis upon which the district court could have issued its second permanent injunction. As outlined below, this court agrees with Medtronic that it should not address the merits of the issue but also agrees with Cross Medical that the district court should have the opportunity to reconsider this question in light of the *First Appeal*.

On the jurisdictional inquiry, this court need not consider whether the district court could have issued the second permanent injunction on some other grounds. Rather, this court reviews the district court's judgment with an eye to whether an alternative basis might support that decision. *See Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 954 (Fed.Cir.1997) (commenting that a cross-appeal is unnecessary for a party to present alternative arguments for *affirmance* of a trial court's decision). In this case, the *First Appeal* determined that material issues of fact remain for adjudication (on both infringement and validity) for claim 5. Those same issues apply as well to claim 7. Thus, even if this court detected flaws in the district court's reasoning on some of the disputed limitations, it could not uphold the district court's grant of summary judgment at this point in the proceedings. Therefore, this court will not address the merits of Cross Medical's theory with respect to infringement of claim 7 by Medtronic's original screws.

While this court does not address the merits of this issue, the *First Appeal* certainly calls into question some of these claim 7 issues. Thus, this court agrees with Cross Medical that this aspect of the district court's summary judgment grant must be vacated and remanded for reconsideration in light of the *First Appeal*. After reconsideration by the district court, the parties may then seek further appellate review of these issues, if necessary.

IV

The district court also determined that claim 7, like claim 5, is not anticipated, obvious, or indefinite. In the *First Appeal*, this court affirmed the district court's holdings on anticipation and indefiniteness with respect to claim 5, but held that issues of material fact remained for adjudication with respect to obviousness. *See First Appeal*, 424 F.3d at 1297. Thus, for similar reasons as discussed in the *First Appeal*, this court affirms the district court's grant of summary judgment of validity on anticipation and indefiniteness with respect to claim 7, reverses its grant of summary judgment of validity on obviousness with respect to claim 7, and remands for further proceedings.

V

In conclusion, summary judgment of non-infringement on all asserted claims should have been entered for Medtronic with respect to the redesigned screws. The remaining issues involving validity and infringement of claim 7 by Medtronic's original screws requires reconsideration in light of the *First Appeal*. Thus this court affirms-in-part, reverses-in-part, vacates-in-part, and remands for further proceedings consistent with this opinion and the *First Appeal*.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED.

RADER, Circuit Judge, concurring.

I concur with the result in this case. I write separately to address further the issue of prosecution history estoppel of claim 5 of U.S. Patent No. 5,474,555 (the '555 patent).

The district court found that Cross Medical successfully rebutted the presumption of prosecution history estoppel for claim 5 of the '555 patent based on tangentiality. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, SA CV

03-311-GLT, slip op. at 10 (C.D.Cal.2005) (*Trial Court Opinion*). With that finding, the district court proceeded to determine that Medtronic's redesigned screws (with internal threads that stopped above the top of the rod) infringe under the doctrine of equivalents. *Trial Court Opinion*, slip op. at 22. As noted in the majority opinion, the '555 patent applicant specifically amended its claims in response to an examiner's rejection. The amendment specified that the first threads extend deeper than the top of the rod received in the channel of the seat. *Majority Opinion*, pp. 1339-40. The examiner allowed the application based on this amendment. *Id.* at 1340.

This prosecution history became very important when Medtronic attempted to design around claim 5. As this court has noted, Medtronic altered its original screw design to terminate the corresponding threads at a position *above* the rod diameter. *Id.* at 1340. Medtronic chose this new design with an eye to the applicant's narrowing amendment. Nonetheless, the district court determined that this narrowing amendment to claim 5 during prosecution was only "tangentially related" to the accused equivalent and thus not subject to an estoppel. *Trial Court Opinion*, slip op. at 8-11; see *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed.Cir.2003) (*en banc*). Thus, the district court found the screws infringe claim 5 under the doctrine of equivalents. *Trial Court Opinion.*, slip op. at 11.

This court made the tangential relation criterion for overcoming the *Festo* presumption very narrow. *Festo*, 344 F.3d at 1369. *Festo* itself recognized that rebuttals under the tangential principle will be rare. *Id.* ("[W]e cannot anticipate the instances of mere tangentialness that may arise...."). Cases in the interim have confirmed *Festo*'s insight; only two cases have successfully invoked the tangential rebuttal principle in this court. *See Insituform Tech. Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1368 (Fed.Cir.2004) (holding that an amendment adding a single cup bore no

more than a tangential relation to the alleged equivalent containing multiple cups); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 849 (Fed.Cir.2006) (finding that the "territory surrendered" by a claim amendment requiring a plate to be "differentially spaced" did not bar equivalence to a dome-shaped structure). The facts of *Insituform* and *Primos* arguably related to situations where the prosecution history clearly demonstrated that the alleged equivalent and the narrowing amendment implicate entirely different aspects of the invention. Yet in reading those cases, frankly, this court might well have justifiably reached a different result in both. For example, in *Insituform*, this court seems to assume that the number of sources bears no relation to the location of those multiple sources. A contrary conclusion might have noted that anytime a technology adds another source it must also add another location for that new source. Multiple sources and locations for those sources would seem logically related.

In my view, the tangential rebuttal principle exacerbates the policy deficiencies of the doctrine of equivalents. Upon invoking tangentiality, the patentee has already admitted that the equivalent falls within the scope of surrendered subject matter. Further, if the case permitted, any patentee would invoke the primary "foreseeability" rebuttal factor. Thus, an invocation of "tangentiality" often admits that the equivalent was both within the scope of the surrender and foreseeable at the time of prosecution. In other words, the patent drafter could have claimed the surrendered and foreseeable technology, but declined to do so.

Furthermore, the tangentiality rebuttal principle, by its nature, undermines principles of public notice. This rebuttal principle operates because the patentee has expounded very different purposes for its narrowing amendment than those applicable to the tangential equivalent. The prosecution record thus does not address this "tangential" equivalent (which nonetheless was surrendered and was known and

claimable during prosecution). In other words, the patentee gets a reward—coverage under the doctrine of equivalents—precisely because its explanations did not give the public any notice of the unclaimed and surrendered subject matter. The public might have believed it could practice technology that the patentee surrendered in prosecution. Moreover, the public might have reasonably undertaken to practice that foreseeable technology because the patentee could have claimed it but declined to do so. Even beyond these principles, the public might have consulted the prosecution history and learned that the patentee gave no explanation for its surrender of this foreseeable technology. Thus, a diligent study of the patent and its prosecution history would give the public every reason to believe that the "tangential" subject matter would fall outside the scope of the invention and within the public domain. The basic principles of public notice would suggest these unclaimed and surrendered "tangential" technologies have no conceivable basis to expect patent protection.

This case is a classic example of the tangentiality principle running counter to principles of public notice. Medtronic had suffered an injunction. It deliberately sought to design around the patented technology—a response that patent law encourages. *State Indus. Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed.Cir.1985) ("One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."). It undoubtedly consulted the patent and adjusted its technology with reference to the claim language and prosecution history of the patent. Then, after it adopted unclaimed technology that the patentee had deliberately surrendered to the public, it finds itself again subject to an injunction. Tangentiality thus, as in this case, can defeat principles of notice and proper procedures for designing

around patented technology. Medtronic's situation illustrates the difficulties of a broad application of tangentiality.

This "tangential" rebuttal principle becomes even more difficult in practice. What neutral standard makes some surrendered and unclaimed technologies infringing equivalents while others enjoy no protection? This tangential concept has no analogue in patent law. How tangential does it have to be?

In any event, this case reaffirms that the tangential rebuttal principle remains very narrow. *See Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed.Cir.2005) (distinguishing *Insituform* as limited to situations in which the prosecution history clearly demonstrates that "the amendment and alleged equivalent involve different aspects of the invention"). *Biagro* thus explains that the factual circumstances that could give rise to the tangential rebuttal principle will very rarely occur (even less often successfully). *Biagro* emphasizes that the evidence of tangentiality must appear in the prosecution history in order to prevent litigation-driven or hindsight reconstruction of the reasons for an amendment. The applicant is not likely to have made a prosecution record that makes some subject matter (the equivalent) tangential to the purpose for the rest of the amendment. *See* Kenneth D. Bassinger, *Unsettled Expectations in Patent Law: Festo & The Moving Target of Claim Equivalence*, 48 How. L.J. 685, 720 (2005) ("Unfortunately, if the reason for an amendment is truly tangential in nature, it is not likely to be found in the prosecution history."); Martha M. Rumore, *Ranbaxy Pharms. v. Apotex: Redefining Claim Drafting and Patent Prosecution Under Festo*, 22 No. 4 Intell. Prop. L. Newsl. (ABA), Summer 2004, at 12, 13 (questioning whether there is, in practice, a separate tangential relation criterion or whether the three criteria established in *Festo* really boil down to simply an all encompassing foreseeability test). In any event, I would reemphasize that the application of the

tangentiality factor in this case preserves the *Biagro* narrowness principle and stress that tangentiality always threatens the public notice that enables designing around.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION.

CROSS MEDICAL PRODUCTS, INC., Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK, INC., et al.,
Defendants.

No. SA CV 03-110GLTANX

May 18, 2004.

2004 WL 5234564

ORDER ON CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT RE: INFRINGEMENT OF THE '555 PATENT

TAYLOR, J.

Plaintiff's motion for partial summary judgment is GRANTED. Defendants' motion for partial summary judgment is DENIED.

I. *BACKGROUND*

Plaintiff Cross Medical Products is the assignee of two patents relating to surgical implant devices used for the fixation and manipulation of the spine, U.S. Patent Nos. 5,466,237 ("the '237 Patent") and 5,474,555 ("the '555 Patent"). The parties' cross-motions for partial summary judgment focus solely on the '555Patent.

The '555 Patent describes an orthopedic surgical implant used to stabilize and align the bones of a patient's spinal column. The invention allows a surgeon to insert a bone screw into the spinal bones of a patient and to place a stabilization rod through the "anchors" of the bone screw of two adjacent spinal bones, fixing the position of the patient's spine.

Plaintiff brought this action against Defendants Medtronic Sofamor Danek, Inc., and Medtronic Sofamor Danek, USA, Inc., alleging infringement of the '237 and '555 patents. Defendants counterclaimed, seeking a declaration of non-infringement and invalidity.

Plaintiff moves for partial summary judgment of infringement of Claim 5 of the '555 Patent. Defendant moves for partial summary judgment of non-infringement on Claim 5.

II. *DISCUSSION*

Summary judgment is proper if "there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c).

A. *Patent Infringement*

In a patent case, the proper construction of the claims of the patent at issue is a question of law for the court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Where the parties do not dispute relevant facts regarding the accused product but disagree over the meaning and scope of the claims, the question of infringement becomes one of claim construction and is appropriate for summary judgment. *Id.*

Infringement analysis involves two steps. First, the claims of the patent must be interpreted and construed by the court. Second, the construed claims must be compared to the accused products to determine whether each claim is found in the accused product. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995). As a

matter of law, a patent claim is not infringed if an element of the claim is not present in the accused device. *Digital Biometrics, Inc. v. Indent, Inc.*, 149 F.3d 1335, 1349 (Fed.Cir.1998).

A party may prove infringement, even without a literal correspondence between the accused device and the claims of the patent, where the differences between the two are insubstantial. *See General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 984 (Fed.Cir.1997). Under this "doctrine of equivalence," a plaintiff must show the accused device "performs substantially the same function in substantially the same way to obtain substantially the same result" as the patented design. *See Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). The Supreme Court in *Warner-Jenkinson v. Hilton Davis Chemical Co.* held the doctrine of equivalence must be applied to the individual elements of the claim, not the invention as a whole. 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). If the accused product does not meet one or more limitations in a claim, either literally or under the doctrine of equivalence, the claim cannot be infringed as a matter of law. *See Id.*; *Netword, LLC v. Central Corp.*, 242 F.3d 1347, 1353-54 (Fed.Cir.2001).

B. *Claim 5 of the '555 Patent*

Claim 5 of the '555 Patent covers an anchor seat means with "an anchor seat portion ... including a channel to receive said rod ... said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis."

Defendants advance four arguments why their products do not infringe this claim. They contend their products do not include: (1) "anchor seat means" that have a "lower bone interface operatively joined to said bone segment [of the spine]"; (2) "securing means" which apply "substantially equal" compressive forces in the direction of the vertical axis

on "either side along said longitudinal axis of said channel"; or (3) a rod that "bear[s] against said channel." Defendants also argue they do not place their devices into patient's spines, which only surgeons do.

1. *"Anchor Seat Means" for Operative Joinder*

Claim 5 requires "an anchor seat means which has a lower bone interface operatively joined to said bone segment...." Defendants argue "operative joinder" requires the screw be secured into the bone so the bottom surface of the anchor seat is joined to the bone, or to washers that sit above the bone. They assert the anchor seat must be joined to the bone to add stability to the rod, and, if the anchor seat were not joined as such, the anchor seat would move freely. Defendants claim their devices rigidly link the rod, the anchor seat, and the screw to the bone segment without joining the anchor seat to the bone segment.

Defendants argue the term "operatively" should be interpreted to mean "to produce an appropriate effect." WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY at 827 (1991). They further argue the effect of providing limited motion and stability between the anchor seat and the bone segment can be found in the patent specification. The Court cannot accept Defendants' proposed definition, which would require incorporation of an additional limitation into the claim.[1] Plaintiff argues the word "operatively" means "involving surgical operations." WEBSTER'S COLLEGE DICTIONARY at 948 (1991). Since the claim language concerns a surgical procedure, this definition is logical. Thus, "operative joinder" in this claim means to "connect during a surgical procedure."[2]

---

[1] "[P]articular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments." *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1346 (Fed.Cir.1999).

[2] "Joined" means "to bring together or in contact; connect," WEBSTER'S COLLEGE DICTIONARY at 728 (1991), or "a surface

Defendants' contentions its products are not designed for stabilization by connecting to the bone are irrelevant because the claim does not refer to the purpose of the connection, and the Court will not read this limitation into the claim. Further, "the accused device, to be infringing, need only be capable of operating in the [infringing] mode ... actual [infringing] mode operation in the accused device is not required." *Intel Corp. v. U.S. Intern. Trade Com'n*, 946 F.2d 821, 832 (Fed.Cir.1991); *see also Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed.Cir.2001)("an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation."). Defendants' devices are capable of operative joinder to the bone segment,[3] and are sometimes used in this way.[4] Defendants' products meet the "operative joinder" limitation of Claim 5.

2. *"Securing Means" and "Substantially Equal Compressive Forces"*

Claim 5 requires "securing means" to "cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel." In other words, when the securing means (a nut) is screwed all

---

forming a common boundary of two bodies." WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY at 631 (1991).

[3] Defendants correctly point out "a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." *High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc.*, 49 F.3d 1551, 1555 (Fed.Cir.1995). However, the rule does not apply in this case because Defendants' products do not need to be altered to connect to the bone segment.

[4] Plaintiff moved for leave to file a surreply to respond to Defendants' evidence on this issue. Since this evidence was not controlling, Plaintiff's arguments are moot.

the way on, it applies a force to the rod, which compresses the rod against the anchor seats and secures the rod in place.

Both parties agree this is a means-plus-function limitation. "[F]or a means-plus-function limitation to read on an accused device, the accused device must employ means identical to or the equivalent of the structures, material, or acts described in the patent specification." *Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042 (Fed.Cir.1993). The question is whether the accused device "performs the function in substantially the same way to achieve substantially the same result." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1435 (Fed.Cir.2000).

Plaintiff argues Defendants' internal nut performs compression in substantially the same way as an outer nut to achieve substantially the same result. Plaintiff cites deposition testimony showing the opposite points of contact on the rod are 180 degrees apart and the screw is intended to be coaxial with the anchor means. Although Plaintiff does not provide tests showing the magnitude of the force on either side, everything before the Court supports the conclusion the forces are substantially equal. Defendants submit no evidence to show the forces are not equal. Viewing the devices themselves and the testimony, it appears Defendants' inner screw meets the limitation of applying substantially equal compressive forces on either side of the channel.

In moving for non-infringement, Defendants urge the Court to interpret Claim 5 to require substantially equal forces on either side of the "channel," not either side of the "vertical axis." Defendants argue this interpretation leads to a finding of non-infringement because their internal screws do not apply compressive forces on the outside of the channel. Even assuming Defendants' interpretation is correct, Defendants' screw would still meet this limitation because it applies forces on either side of the channel.

Defendants provide no support for their additional limitation requiring the force be applied on the outside of the channel.

3. *"Bear Against Said Channel"*

Defendants contend none of their products meet Claim 5's requirement that the rod bear against the channel. In its February 11, 2002 Order in the AcroMed case,[5] the Court held AcroMed's "pressure disk," which was physically between the rod and the anchor means, did not avoid infringement. This Court held "Claims 5 and 7 broadly cover an anchor seat with a channel through which the stabilization rod runs and upon which the rod bears. There is nothing in the claim language which excludes an anchor channel composed of more than one component part." February 11, 2002 Order at 6:16-19. Defendants claim their products do not meet this limitation because their products contain a crown which bears against the rod, and the crown is not joined to the anchor means like the swedged pressure disks in AcroMed products.

Plaintiff argues Defendants' crowns are physically joined to the anchor means because they cannot be removed without breaking the screw. Sherman Depo. at 123:8-124:1; 246:1-247:2. Defendants do not respond to this evidence, and they continue to insist their crowns are free-floating because there is no type of lock between the crown and the anchor means. Defendants have not given the Court a reason to depart from the previous ruling. Even if the crowns are not physically joined to the anchor means, "there is nothing in the claim language which excludes an anchor channel composed of more than one part." Defendants' products infringe on this portion of Claim 5.

4. *Surgeon Implantation*

---

[5] *Cross Medical Products, Inc. v. DePuy Acromed, Inc., et al.*, SA CV 00-876-GLT (ANx).

Defendants argue Claim 5 defines a spinal fixation device that is already implanted in the spine because otherwise the "bone interface" of the anchor seat is not "operatively joined" to the spine. They further argue they cannot be liable as infringers because they do not implant products in a patient's spine—the surgeons do. This argument is questionable. In any event, under 35 U.S.C. § 271 Defendants can be liable for inducing the infringement or for selling a device which constitutes part of the invention.

III. *DISPOSITION*

Plaintiff's motion for partial summary judgment is GRANTED. Defendants' motion for partial summary judgment is DENIED.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION.

CROSS MEDICAL PRODUCTS, INC., Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK, INC., et al.,
Defendants.

No. SA CV 03-110GLTTANX.

Aug. 19, 2004.

2004 WL 5234565

ORDER ON CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT RE: INVALIDITY OF THE '555 PATENT

TAYLOR, J.

CALENDAR ITEM # 10

Defendants' motions for partial summary judgment are DENIED. Plaintiff's motions for partial summary judgment are GRANTED.

I. *BACKGROUND*

Plaintiff Cross Medical Products is the assignee of two patents relating to surgical implant devices used for the fixation and manipulation of the spine, U.S. Patent Nos. 5,466,237 ("the '237 Patent") and 5,474,555 ("the '555

Patent"). The '555 Patent describes "an orthopedic surgical implant used to stabilize and align the bones of a patient's spinal column." The invention allows a surgeon to insert a bone screw into the spinal bones of a patient and to place a stabilization rod through the "anchors" of the bone screw of two adjacent spinal bones, fixing the position of the patient's spine.

Plaintiff brought this action against Defendants Medtronic Sofamor Danek, Inc., and Medtronic Sofamor Danek, USA, Inc., alleging infringement of the '237 and '555 patents. Defendants counterclaimed, seeking a declaration of non-infringement and invalidity.

The parties both move on invalidity of Claim 5 of the '555 Patent.

II. *DISCUSSION*

Summary judgment is proper if "there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c).

A patent is presumed valid, and each claim of a patent is presumed valid independently of the validity of other claims. 35 U.S.C. § 282. "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

Defendants, as the parties asserting invalidity, must overcome the presumption of validity by clear and convincing evidence. *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 725 (Fed.Cir.2002). The burden of overcoming the presumption by clear and convincing evidence applies to a motion for summary judgment seeking invalidity. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed.Cir.1991).

A. *Claim Construction*

"[C]laim construction ... begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998). The proper construction of the claims of the

patent at issue is a question of law for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

In order to properly construe a patent claim, the Court must first consider such "intrinsic evidence" as the claim language, the specification of the patent, and the prosecution history. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 979 (Fed.Cir.1995), *aff'd* at 513 U.S. 370. While the Court may also consider such "extrinsic evidence" as expert testimony, inventor testimony, and other reference materials, this evidence is used "for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id.* at 986.

The parties dispute whether Claim 5 of the '555 patent covers monoaxial screws or if it is limited to polyaxial screws. Defendants argue Claim 5 includes monoaxial screws and does not require the anchor seat and screw be separate pieces. Most of Defendants' arguments were addressed in a previous ruling in the related *AcroMed* case,[1] and the Court agrees with its prior decision.

Claim 5 covers an "anchor seat means" with "an anchor seat portion ... including a channel to receive said rod ... said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis." As the Court previously held in the *AcroMed* ruling, although the claim language itself does not indicate whether the screws are polyaxial or monoaxial, the specifications and the drawings establish the claims are limited to polyaxial screws. *AcroMed* Ruling at 8.

Defendants argue the Court should not limit the claim language by reading in the polyaxial movement or

---

[1] *Cross Medical Products, Inc. v. Depuy AcroMed, Inc.*, SACV 00-876-GLT(ANx), Order on Parties' Motions for Summary Judgment of Validity and Acromed's Defenses, January 9, 2003 ("*AcroMed Ruling*").

separability features of the specification. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir.1998) ("limitations from the specification are not to be read into the claims...."). Plaintiff correctly contends the Court's previous interpretation is proper because "anchoring means" and "anchor seat means" are "means-plus-function" limitations, which must be construed by referring to the specification. "Typically, if the word 'means' appears in a claim element in combination with a function, it is presumed to be a means-plus-function element ..." *Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356 (Fed.Cir.1999). The Court adheres to the reasoning in its previous decision in the *AcroMed* case, which properly construed the claim in light of the specification.

Defendants next argue the prosecution history and the claim differentiation doctrine reinforce that Claim 5 covers monoaxial screws. Citing to a 1993 Annual Report which shows Plaintiff added a monoaxial screw to its line, Defendants assert Plaintiff sought patent protection for this new product through Claim 5. Even if the Court considers this extrinsic evidence, it does not support Defendants' assertion.

The doctrine of claim differentiation creates a "presumption that each claim in a patent has a different scope." *Comark Communs. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998). Defendants argue since Claim 1 requires polyaxial screws, that limitation cannot be read into Claim 5 or the two claims would not be different. *See Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1326 (Fed.Cir.2003). Claim 5, however, is already broader than Claim 1 because it requires micro-motion and Claim 5 does not. (The Court has received the parties' additional briefing on this issue, and the result does not change.)

Defendants contend the doctrine of marking estoppel precludes Plaintiff from arguing Claim 5 does not cover monoaxial screws. Although Plaintiff marked its monoaxial

screws with the '555 patent number for seven years, claims cannot be construed based on a party's marking of products, which amounts to extrinsic evidence of the claim language. The marking estoppel cases cited by Defendants concern former licensees who were estopped from arguing noninfringement after they marked their products with the patent number, and they are not applicable to the current case.

B. *Anticipation*

A claim is anticipated under 35 U.S.C. § 102 if clear and convincing evidence demonstrates that a single prior art reference discloses, either expressly or inherently, each limitation of the claim. Anticipation is a question of fact, and is determined by first construing the claims and then comparing the properly construed claims to the prior art. *In re: Cruciferous Sprout Litigation*, 301 F.3d 1343, 1346 (Fed.Cir.2002).

Defendants contend Claim 5 is anticipated by the Webb '444 patent and the Byrd-Transpedicular Spinal Fixator. Both of these inventions disclose monoaxial screws, not polyaxial screws, so they lack this limitation of Claim 5.

Defendants' motion for summary judgment on anticipation is DENIED, and Plaintiff's cross-motion is GRANTED.

C. *Obviousness*

"A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

Obviousness is an issue of law to be determined by the Court based on a series of factual findings. To find a patent obvious, a Court must determine: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art;

and (4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-28, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); *accord Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447 (Fed.Cir.1986). When an obviousness challenge is based on multiple prior art references, there must be a showing of some teaching, suggestion, or reason to combine the references. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed.Cir.1997).

Defendants contend Claim 5 is obvious in view of the Puno '602 Patent, the Web '644 Patent, and the Byrd-Transpedicular Spinal Fixator. The parties do not contest the '602 and '644 Patents are prior art, however, Plaintiff argues the Byrd device is not prior art. Since Dr. Puno, one of the '555 Patent inventors, also invented the closure mechanism found in the Byrd device, the Byrd device was not invented by a third party and is not prior art. 35 U.S.C. § 102(f).

The '602 and '555 patents are both polyaxial spinal implant devices. The only major difference between the '602 patent and the '555 is the '602 device is tightened from the bottom and the '555 is a top-loading nut. The '644 patent covers a top-loading monoaxial spinal implant device.

The parties disagree on whether there was some motivation to combine these prior art references. Plaintiff relies on the Court's previous ruling in the *AcroMed* case. In that case, *AcroMed* argued the top-loading nut would have been obvious in light of the problem to be solved, i.e. surgeons having difficulty tightening the bottom-loading nuts during implantation. The Court found *AcroMed* failed to show motivation to combine because "the problem was not discovered by looking at the prior art or the patent itself. It was only discovered when doctors tried to use the product." *AcroMed* Ruling at 15. The Court relied on *In re Sponnoble*, 56 C.C.P.A. 823, 832, 405 F.2d 578 (1969), which held "a patentable invention may lie in the discovery

of the source of a problem even though the remedy may be obvious once the source of the problem is identified."

The Court adheres to its prior reasoning. Here again, Defendants offer no evidence the problem was previously disclosed in the prior art. Defendants cite only the '555 patent to describe the problem the '555 patent sought to fix. Although Defendants argue the clinical investigators identified the problem with the bottom-loading nut, the investigators' letters are not prior art.

Defendants correctly note the motivation to combine need not be explicit in the prior art; "it can be implicit in the knowledge of one of skill in the art." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1337 (Fed.Cir.2004). This rule does not change the result in this case because it does not relate to identification of the problem.

Defendants' motion for summary judgment of obviousness is DENIED, and Plaintiff's cross-motion is GRANTED.

D. *Indefiniteness*

35 U.S.C. § 112(2) requires a patent "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention". This is the "definiteness" requirement.

The primary inquiry in determining whether a patent is invalid for indefiniteness is whether a person of ordinary skill in the art would understand what is being claimed. *Amgen, Inc. v. Chugai Pharma. Co.*, 927 F.2d 1200, 1217 (Fed.Cir.1991). The claims, when read in light of the patent's specification, must reasonably apprise those skilled in the art of the scope of the invention to survive an indefiniteness challenge. *Personalized Media Comms., LLC v. International Trade Comm'n*, 161 F.3d 696, 705 (Fed.Cir.1996). A determination of claim indefiniteness is a legal conclusion that is drawn from the Court's performance of its duty as the construer of patent claims. *Id.*

Defendants argue Claim 5 is indefinite because it requires "the application of substantially equal compressive forces ... on either side along said longitudinal axis of said channel," but it does not refer to a longitudinal axis elsewhere in the claim. "[T]he failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite." *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359 (Fed.Cir.2001). The Court has considered all of Defendants' arguments regarding indefiniteness and concludes the scope of this claim is ascertainable. It refers to the long axis of the channel, and the Court has already construed this language in its previous summary judgment order on infringement.

Defendants' motion for summary judgment on indefiniteness is DENIED, and Plaintiff's cross-motion is GRANTED.

III. *DISPOSITION*

Defendants' motions for summary judgment on anticipation, indefiniteness, and obviousness are DENIED, and Plaintiff's cross-motions are GRANTED.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

CROSS MEDICAL PRODUCTS, INC., Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK, INC., et al.,
Defendants.

No. SA CV 03-1110GLTANX

April 11, 2005

2005 WL 5239258

ORDER ON (1) CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT RE: INFRINGEMENT OF CLAIM 5 OF THE '555 PATENT; (2) CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT RE: INFRINGEMENT OF CLAIM 7 OF THE '555 PATENT; (3) PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT RE: INVALIDITY AND DEFENDANTS' AFFIRMATIVE DEFENSES REGARDING CLAIM 7 OF THE '555 PATENT AND RELATED COUNTERCLAIMS

TAYLOR, J.

I. *BACKGROUND*

Plaintiff is the assignee of U.S. Patent No. 5,474,555 ("the '555 Patent"), which relates to an orthopedic surgical implant used to stabilize and align the bones of a patient's spinal column. The invention allows a surgeon to insert a bone screw into the patient's vertebra and place a stabilization rod through the "anchors" of the implants in two adjacent vertebrae, fixing the position of the patient's spine.

Plaintiff brought this action against Defendants Medtronic Sofamor Danek, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic"), alleging infringement of the '555 Patent. Defendants counterclaimed, seeking a declaration of non-infringement and invalidity.

In a May 18, 2004 Order, this Court granted Plaintiff's motion for partial summary judgment of infringement of claim 5 of the '555 Patent and denied Medtronic's motion for partial summary judgment of non-infringement of claim 5. On August 19, 2004 the Court granted Plaintiff's motion for partial summary judgment of validity of claim 5 and denied Medtronic's motion for partial summary judgment of invalidity. On September 27, 2004, the Court granted Plaintiff's motion for a permanent injunction. The Court issued the permanent injunction on October 4, 2004, but stayed the injunction for 90 days to allow Medtronic to appeal. Medtronic appealed to the Federal Circuit on October 13, 2004.

In the meantime, Medtronic redesigned its polyaxial screws found by the Court to infringe claim 5. The Court now considers the parties' cross-motions for partial summary judgment of infringement of claim 5 by the new screw designs.

The parties also filed cross-motions for partial summary judgment of infringement of claim 7 by the old and new polyaxial screw designs. Plaintiff filed a motion for partial summary judgment as to invalidity and Medtronic's other affirmative defenses regarding claim 7.

II. *DISCUSSION*

A. *Legal Standards*

1. *Summary Judgment*

Summary judgment is proper if "there is no genuine issue as to any material fact" and "the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c).

2. *Literal Infringement*

Infringement analysis involves two steps. First, the claims of the patent must be interpreted by the Court. The proper construction of the claims is a question of law for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Where the parties do not dispute relevant facts regarding the accused product but disagree over the meaning and scope of the claims, the question of infringement becomes one of claim construction and is appropriate for summary judgment. *Id.*

To construe a patent claim, the Court "seeks to accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1116 (Fed.Cir.2004). The Court first considers intrinsic evidence such as the claim language, the specification of the patent, and the prosecution history. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

Claim language must be given its ordinary meaning as understood by persons skilled in the art. *Tex. Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002). Dictionaries, encyclopedias, and treatises may be used to determine ordinary meaning. *Id.* "Claims must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979. However, the Court may not read a limitation from the specification into a claim if the limitation is not present in the claim language. *Liebel-*

Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed.Cir.2004).

While the court may also consider such extrinsic evidence as expert testimony, inventor testimony, and other reference materials, this evidence is used "for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981.

Next, the construed claims must be compared to the accused product to determine whether each claim is found in the product. *See id.* at 976. A patent claim is not infringed if an element of the claim is not present in the accused device. *Digital Biometrics, Inc. v. Indentix, Inc.*, 149 F.3d 1335, 1349 (Fed.Cir.1998).

3. *Doctrine of Equivalents Infringement*

A party may prove infringement, even without a literal correspondence between the accused device and the claims of the patent, where the differences between the two are insubstantial. *See Gen. Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 984 (Fed.Cir.1997). Under this "doctrine of equivalents," a plaintiff must show the accused device "performs substantially the same function in substantially the same way to obtain substantially the same result" as the patented design. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). Analysis of the role of each claimed element in the context of the claim informs the inquiry "as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

The doctrine of equivalents is applied to the individual elements of the claim, not the invention as a whole. Id. at 29. If the accused product does not meet one or more limitations in a claim, either literally or under the doctrine of

equivalents, the claim cannot be infringed as a matter of law. *See id.; Netword, LLC v. Cent. Corp.*, 242 F.3d 1347, 1353-54 (Fed.Cir.2001).

The doctrine of equivalents may not eliminate an element of a claim entirely or "vitiate the central functions of the patent claims." *Warner-Jenkinson*, 520 U.S. at 29-30. A device can infringe under the doctrine if it substitutes an equivalent component, as long as it does not enlarge "the metes and bounds of the invention *beyond* what is claimed." *Id.* at 29 (internal quotation omitted). The Supreme Court has identified the "essential inquiry" as whether the accused product contains elements "identical or equivalent to each claimed element of the patented invention." *Id.* at 40.

4. *Prosecution History Estoppel*

"[P]rosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by amendment or argument." *DeMarini Sports v. Worth, Inc.*, 239 F.3d 1314, 1332 (Fed.Cir.2001). "[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). Whether prosecution history estoppel applies is a question of law for the Court. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367-68 (Fed.Cir.2003).

The accused infringer must first show the amendment narrowed the literal scope of the claim. *Id.* at 1366. If it did, the patent holder may show the amendment was not for purposes of patentability. *Festo*, 535 U.S. at 739-40. If the amendment narrowed the claim and was made for purposes of patentability, the Court considers the scope of the subject matter surrendered by the amendment. *Festo*, 344 F.3d at 1367. It is presumed the patentee gave up all subject matter between the original and amended claim limitations. *Id.*

The patentee may overcome this presumption in three ways, each of which demonstrate "the amendment does not surrender the particular equivalent in question." *Festo,* 535 U.S. at 740. First, "[t]he equivalent may have been unforeseeable at the time of the application." *Id.* Second, "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question." *Id.* Third, "there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-41. If the patentee rebuts the presumption, prosecution history estoppel does not apply, and infringement may be found based on the doctrine of equivalents. *Festo,* 344 F.3d at 1367.

B. *Infringement of Claim 5*

Plaintiff contends Medtronic's new screw design infringes claim 5 of the '555 Patent literally and under the doctrine of equivalents. Claim 5 requires a "seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel."

1. *Literal Infringement*

The only difference between the old and new screw designs is the new design replaces the threads below the top of the rod with a groove or "undercut." The parties dispute whether the undercut meets the claim limitation requiring threads extending to a depth below the top of the rod.

Plaintiff argues the undercut is an "effective thread," which the parties agree is a complete thread, plus portions of an incomplete thread that are fully formed at the root but not at the crest.[1] Plaintiff argues the flat surface of the undercut is a fully-formed, elongated root.

---

[1] Plaintiff cites a definition from *Machinery's Handbook.* (Finkelstein Decl. Ex. D.) Medtronic does not propose an alternate definition and

The Court disagrees. The definition of a root is the "surface of the thread which joins the flanks of adjacent thread forms." (Finkelstein Decl. Ex. D at 57.) The undercut does not "join the flanks" of any thread forms because there are no thread forms in the undercut. The undercut is a flat surface and cannot be construed as a root. Because the new screw design does not contain "portions of an incomplete thread which are fully formed at the root," it is not an effective thread. The new design does not literally meet the limitation requiring "threads" extending below the top of the rod.[2]

As an alternate basis of non-infringement, Medtronic argues its new screw designs do not meet the "operative joinder," "securing means," and "substantially equal compressive forces" limitations of claim 5. The Court already found Medtronic's old screw designs infringe these claim limitations. (*See* May 18, 2004 Order.) Because the parties agree the only structural difference between the old and new screw designs is the undercut, the new screws do not have any characteristic justifying a change to the Court's earlier infringement ruling. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111 (Fed.Cir.2004), cited by Medtronic as "recent Federal Circuit

---

apparently agrees Plaintiff's definition is appropriate. Courts may look to technical definitions rather than general dictionaries when terms have special meanings in the art. *Tex. Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002) ("'Technical treatises and dictionaries ... are worthy of special note. Judges are free to consult such resources at any time ... and may also rely on dictionary definitions when construing claim terms ....'") (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n. 6 (Fed.Cir.1996)) (omissions in original). Here, technical definitions for the components of screws are appropriate.

[2] Medtronic's alternative argument is not persuasive. It contends the undercut is not an effective thread because it is deeper than, and has a bigger diameter than, the complete thread. Medtronic does not cite authority showing the diameter or depth of a thread must be constant to meet the definition of a "thread."

jurisprudence," does not change the Court's previous finding of infringement of the "operatively joined" limitation. The Court adheres to its past claim constructions and infringement rulings on these claim limitations.

2. *Prosecution History Estoppel*

Medtronic argues Plaintiff cannot use the doctrine of equivalents to assert infringement of claim 5 because Plaintiff narrowed claim 5 during prosecution of the patent. Before the amendment, the claim stated: "said seat means including a vertical axis and first threads." (Finkelstein Decl. Ex. E at 133.) After the amendment, the claim reads: "said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel." (Finkelstein Decl. Ex. E at 147.)

The additional limitations with respect to the threads—extending along the vertical axis, extending toward the lower bone interface, and extending to a depth below the diameter of the rod—narrowed the scope of the claim. Threads extending along the horizontal axis, away from the lower bone interface, or to a depth above the diameter of the rod are excluded from the literal scope of the claim.

Plaintiff's argument, that the amendment did not narrow the claim because the only thing excluded by the amendment is a non-functioning device, is not persuasive. The amendment narrowed the claim with respect to the type of threads falling within the scope of the claim. The Court looks to the language of the particular claim limitation to determine if the limitation is narrowed. *See Festo,* 344 F.3d at 1371 (finding an amendment adding an additional limitation to a previously claimed element was a narrowing amendment). Plaintiff cites no authority showing it is appropriate for the Court to look to the device as a whole and hypothesize whether a device described by the pre-amendment claim limitations would work.

Next, the parties do not dispute the amendment was made for purposes of patentability. Because the amendment narrowed the claim and was made for purposes of patentability, it is presumed the patentee gave up all subject matter between the original and amended claim limitations. *Festo*, 344 F.3d at 1367. Here, the relevant subject matter is an anchor seat means with threads extending to a depth above the diameter of the rod.

However, Plaintiffs rebuts this presumption by showing the rationale underlying the amendment was no more than tangentially related to Medtronic's new screw design. *See Festo*, 535 U.S. at 740. The prosecution history explains the rationale for the amendment. The patent examiner rejected the initial claim for having an inadequate written description under 35 U.S.C. § 112 ¶ 1, being indefinite under § 112 ¶ 2, and being anticipated by the Puno '602 patent under § 102(b). (Finkelstein Decl. Ex. E at 137-40.) The applicant then amended the thread limitation of the claim. The applicant explained the amendment was "[i]n response to the rejection under 35 U.S.C. 112" and was for the purpose of defining a device in which the rod could be captured between the securing means (such as a nut) and the channel. (Finkelstein Decl. Ex. E at 148.)

The patent examiner's notes confirm this rationale for the amendment. The examiner wrote the claims would be amended to add the thread limitation "to reflect" a securing means fitting "securely over the rod without the cap." (Finkelstein Decl. Ex. E at 143.)

This evidence shows the rationale behind the amendment was to adequately describe and enable a device, under § 112, in which the securing means could secure the rod without the use of a cap. The applicant was not attempting to overcome prior art using an undercut, and the amendment did not relate to an undercut. Therefore, the rationale was no more than tangentially related to Medtronic's new screw design, in which threads extend part

of the way toward the rod and an undercut extends to a depth below the top of the rod. Medtronic's new screw design is "beyond a fair interpretation of what was surrendered." *Festo,* 535 U.S. at 738.

Medtronic asserts the prosecution history does not show how the applicant overcame the anticipation rejection. This means, Medtronic argues, it is presumed Plaintiff gave up all subject matter between the original and amended claim limitations. Absence of an explanation for an amendment is relevant for determining whether the amendment was made for purposes of patentability. *Festo,* 535 U.S. at 739-40. Here, the parties agree the amendment was for purposes of patentability, and the Court applied the presumption. The lack of explanation for the anticipation rejection does not show the reason stated for the amendment by both the applicant and the examiner—to overcome the § 112 rejection—is incorrect.

Even if the amendment were related to the anticipation rejection, Medtronic has not shown the Puno '602 patent disclosed an undercut extending to a depth below the rod. Plaintiff asserts the Puno '602 patent does not disclose this structure, and it appears in the diagrams provided to the Court that it does not. (*See* Medtronic's Cross-Mot./Opp'n at 23; Pl.'s Opp'n/Reply at 16.) Medtronic's argument does not defeat Plaintiff's showing of a rationale no more than tangentially related to Medtronic's new screw design.

Having found Plaintiff has rebutted the presumption based on the tangential relation exception, the Court does not reach the other two exceptions. Prosecution history estoppel does not apply. Plaintiff may assert infringement under the doctrine of equivalents.

3. *Doctrine of Equivalents*

Medtronic's new screw design, containing a complete thread and an undercut, performs substantially the same function (enabling the securing means to reach a depth below the top of the rod) in substantially the same way (by

cooperating with the threads of the securing means) to achieve substantially the same result (to capture the rod between the securing means and the channel), as do threads extending to a depth below the diameter of the rod. A combination of components may infringe under the doctrine of equivalents even if the patented invention claims a single component. *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398 (Fed.Cir.1994).

The thread-plus-undercut design cooperates with the threads of the securing means by interacting with the threads most of the way to the rod and allowing the securing means to pass through the undercut to reach the rod. Complete threads cooperate with threads of the securing means by interacting with the threads the whole way and allowing the securing means to pass through the threads to reach the rod. The way in which these structures achieve the same function is substantially the same. That the undercut does not interact with the threads of the securing means over the relatively short distance from the bottom of the threads to the rod is insubstantial because the threads interact with the securing means over most of the distance from the top of the anchor seat to the rod.

Deposition testimony of Medtronic's corporate designee shows the new design performs substantially the same function in substantially the same way to achieve substantially the same result. He testified both the old and new designs "work[ ] the same." (Finkelstein Decl. Ex. B at 26:1.) Also, the undercut "doesn't change the functionality at all. The thread continues down until it can push against the rod in either case." (Finkelstein Decl. Ex. B at 26:8-11.)

Medtronic argues the threads-plus-undercut design functions in a substantially different way than a fully threaded design. Full threads intermesh "over the full distance of the anchor seat," (Medtronic's Cross-Mot./Opp'n at 14) while the threads-plus-undercut design intermeshes threads over a shorter distance. Medtronic contends this

creates a lesser degree of force. Any such difference is insubstantial.

First, Medtronic does not cite evidence showing the undercut design applies a lesser degree of force between the securing means and the rod. Given the relatively short distance over which Medtronic's screw passes through the undercut, it is not readily apparent why this would be so. Second, even if there is a lesser degree of force in the new design, Medtronic does not show why this difference is substantial. Medtronic's representative testified there is no functional difference between the old and new screw designs.

Medtronic informed the Food and Drug Administration ("FDA") that the new product presented "insignificant changes in design" (Finkelstein Decl. Ex. G at 191) and is "as safe and effective as its old pedicle screw." (Medtronic's Reply at 8). Although the Court does not rely on these statements to the FDA in finding infringement, they raise questions about the credibility of Medtronic's unsupported attorney argument that the new design offers "less security" than the old design, and that the differences between claim 5 and the new design are substantial. (*See, e.g.,* Medtronic's Reply at 8.)

Finding the thread-plus-undercut structure is equivalent to a threaded structure does not vitiate the claim limitation requiring threads extending to a depth below the top of the rod. Medtronic's new screw design has a structure, the undercut, corresponding to the claimed threads.[3] The undercut performs substantially the same function in substantially the same way to achieve substantially the same

---

[3] Medtronic's attorneys' statement, "[w]hen Medtronic redesigned its pedicle screws, it removed a limitation (anchor seat threads extending below the diameter of the rod) *without substituting another in its place,"* is untenable. (Medtronic's Reply at 6 (emphasis added).) Medtronic's corporate designee testified the new design *added* the undercut. (Finkelstein Decl. Ex. B at 22:9-15.)

result as threads extending to a depth below the top of the rod.

The language of the claim does not specifically exclude an undercut structure. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed.Cir.2001); *Dolly, Inc. v. Spaulding & Evenflo Co.*, 16 F.3d 394, 400 (Fed.Cir.1994). To find otherwise would be to reduce the doctrine of equivalents "to nothing more than a repeated analysis of literal infringement." *Ethicon Endo-Surgery v. United States Surgical Corp.*, 149 F.3d 1309, 1317 (Fed.Cir.1998).

4. *Conclusion*

Medtronic's new screw design infringes claim 5 of the '555 Patent under the doctrine of equivalents. Plaintiff's motion for partial summary judgment of infringement of claim 5 is GRANTED. Medtronic's cross-motion is DENIED.

C. *Infringement of Claim 7*

Plaintiff contends Medtronic's old and new screw designs infringe claim 7 of the '555 Patent under the doctrine of equivalents.

1. *Whether the Claim is Barred*

Medtronic argues Plaintiff is barred from bringing this claim because it supplemented its interrogatory responses to add the claim after discovery closed.

The Court will consider the cross-motions on the merits. Although Plaintiff added the claim after the close of discovery, it appears Medtronic is not unduly prejudiced. Claim 7 is part of the same '555 Patent as claim 5, for which the parties have conducted discovery, and on which the Court has already decided several motions. It does not appear any new discovery is required with respect to claim 7. The same accused products are at issue. Medtronic does not state what additional discovery it would need, and it did not move to continue the motion under Federal Rule of Civil

Procedure 56(f) to take additional discovery. Both parties have fully briefed the motions relating to claim 7. Considering the merits of these motions will further the goal of resolving all issues in this lengthy litigation as soon as possible.

Medtronic also argues Plaintiff is barred from relying on the doctrine of equivalents for claim 7 due to prosecution history estoppel. For the reasons prosecution history estoppel does not bar Plaintiff on claim 5, discussed above, it also does not bar Plaintiff from asserting the doctrine of equivalents on claim 7.

2. *Infringement*

a. *Old and New Screws*

Medtronic asserts its old and new screws do not infringe the limitation of claim 7 requiring "anchors each comprising screw means, an anchor seat, and a nut." Medtronic's old and new screw designs use an internal set screw instead of a nut.

This Court previously found Medtronic's internal set screw literally infringes the "securing means" and "substantially equal compressive forces" limitations of claim 5 because it performs the same function as a nut in substantially the same way to achieve substantially the same result. (May 18, 2004 Order at 6-7.) The test applied in the previous Order is similar to the doctrine of equivalents test applied here, where the Court must determine if a set screw is equivalent to a nut.

The doctrine of equivalents cannot be used to vitiate a claim limitation in favor of a structure specifically excluded from the claim language. *Warner-Jenkinson,* 520 U.S. at 29-30; *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1582 (Fed.Cir.1996) (citing *Dolly, Inc. v. Spalding & Evenflo Co.*, 16 F.3d 394 (Fed.Cir.1994)). Here, finding a set screw is equivalent to a nut does not vitiate the "nut" limitation. That a set screw does not literally meet the limitation does not necessary mean a set screw is specifically excluded from the

limitation. *See Ethicon Endo-Surgery v. United States Surgical Corp.*, 149 F.3d 1309, 1317 (Fed.Cir.1998). A device is specifically excluded if "its inclusion is somehow inconsistent with the language of the claim," or if it is directly addressed by the claim and specifically excluded. *Id.* at 1316-17. A set screw is not directly addressed by the claim, and its inclusion is not inconsistent with the claim.

Having previously found a set screw performs the same function as a nut in substantially the same way to achieve substantially the same result, the Court now applies its prior ruling here, to find the set screw infringes the nut limitation of claim 7 under the doctrine of equivalents.[4]

Medtronic's old and new screw designs do not infringe the limitation of claim 7 requiring an "anchor seat including external threads." Medtronic's devices have an anchor seat with internal threads. To find Medtronic's devices equivalent to the claim limitation would vitiate the structural requirement of external threads. The claimed structure, "external threads," specifically excludes internal threads. *See Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed.Cir.2000) (finding the limitation "majority of the length" was not equivalent to a structure covering a minority of the length); *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1582 (Fed.Cir.1996) (holding a limitation requiring three offset distances specifically excluded a device with two offset distances).

This case is distinguishable from *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251 (Fed.Cir.1989). There, a negative charge in one structure of

---

[4] Medtronic argues its set screw does not meet the limitation requiring the nut to be "exterior to said rod." It appears Medtronic treats this limitation as requiring a nut exterior to the anchor seat, not the rod. Neither party proposes a claim construction for the "exterior to said rod" limitation, and it is not apparent to the Court what this limitation means. Without a proposed claim construction, the Court cannot decide whether Medtronic's set screw infringes the claim limitation.

the device was equivalent to a positive charge in another structure of the device because, in both configurations, the two structures combined to produce a positive charge. *Id.* at 1260-61. Here, it is not just the characteristic of a claimed structure that is different, but the structure itself. An anchor seat with internal threads is a different structure than an anchor seat with external threads.

For the same reason, Medtronic's screws also do not meet the structural limitation requiring a nut with a "bore having threads which mate with the threads of the anchor seat." This limitation requires the bore through the center of the nut have threads; in other words, a nut with internal threads. In Medtronic's devices, the set screw has a bore through the center, but the bore does not have threads. The set screw has external threads. Medtronic's devices do not infringe this claim limitation under the doctrine of equivalents.

Medtronic also argues its old and new screws do not meet the limitation "anchor seat including ... a channel to receive said rod and having a rod contacting surface in the bottom of the channel." Medtronic apparently argues its devices do not meet these limitations because there is a separate "crown member" between the rod and the screw head.

This appears to be the same argument previously made to this Court with respect to the "bear against said channel" limitation of claim 5. In the May 18, 2004 Order, this Court found Medtronic's old screws literally infringe the "bear against said channel" limitation. The crown members did not defeat infringement because "'there is nothing in the claim language which excludes an anchor channel composed of more than one part.'" (May 18, 2004 Order at 8 (quoting Feb. 11, 2002 Order in *Cross Medical Products, Inc. v. DePuy Acromed, Inc.*, SA CV 00-876-GLT (ANx)).)

Claim 7 also does not exclude an anchor channel composed of more than one part. Medtronic has given this

Court no reason to depart from its previous ruling. The crown member does not defeat literal infringement of the "channel to receive said rod" or "rod contacting surface in the bottom of the channel" limitations of claim 7.

b. *New Screws*

Medtronic finally contends its new screws do not meet the claim limitation: "said threads extending toward the rod contacting surface to a thread run-out, the distance between the rod contacting surface and the thread run-out being less than the diameter of the rod."

Plaintiff contends Medtronic's new screws literally infringe this limitation because the undercut is a "thread run-out." A thread run-out is the "portion of the incomplete thread which is not fully formed at the root or at crest and root." (Finkelstein Decl. Supp. Mot. Infringement Claim 5 of '555 Patent Ex. D at 58.) An incomplete thread, in turn, is "[a] threaded profile having either crests or roots or both, not fully formed, resulting from their intersection with the cylindrical or end surface of the work or the vanish cone." (Finkelstein Decl. Supp. Mot. Infringement Claim 5 of '555 Patent Ex. D at 55.)

An undercut does not meet the definition of a thread run-out, which requires either partially formed crests or partially formed roots. As discussed above with respect to infringement of claim 5, the undercut is not a root. It follows the undercut is not a partially formed root. An undercut also is not a crest, which is defined as the surface of a helical projection. (Finkelstein Decl. Supp. Mot. Infringement Claim 5 of '555 Patent Ex. D at 60, 66.) There is no helical projection in the undercut. Because the undercut is not a crest, it also is not a partially formed crest. Medtronic's new screws do not literally infringe this claim limitation.

Plaintiff also asserts infringement under the doctrine of equivalents. The Court found above the undercut infringes the limitation in claim 5, "threads with extend ... to a depth below the diameter of the rod when it is in the rod receiving

channel." For the same reasons, the new screw design also infringes the limitation of claim 7, "the distance between the rod contacting surface and the thread run-out being less than the diameter of the rod," under the doctrine of equivalents.

c. *Conclusion*

Because Medtronic's old and new screw designs do not infringe at least one limitation of claim 7, either literally or under the doctrine of equivalents, Plaintiff's motion for partial summary judgment of infringement of claim 7 is DENIED, and Medtronic's cross-motion is GRANTED.

D. *Invalidity of Claim 7 and Other Affirmative Defenses*

In response to Plaintiff's claim of infringement of '555 Patent, Medtronic raised an affirmative defense of invalidity and counterclaimed for declaratory judgment of invalidity of the '555 Patent. Plaintiff now brings a motion for partial summary judgment of validity of claim 7 of the '555 Patent.[5]

In an August 19, 2004 Order, this Court found claim 5 of the '555 Patent is valid because it is not anticipated, not obvious, and not indefinite. Medtronic now states claim 7 is invalid and unenforceable "for the very same reasons" claim 5 is invalid and unenforceable.[6] (Medtronic's Opp'n at 4.) Specifically, Medtronic argues claim 7 is invalid as obvious in light of the combination of the Puno '602 patent and the Webb '644 patent. Medtronic contends the Marnay '913 patent provides a motivation to combine the Puno '602 and Webb '644 patents.

---

[5] For the same reasons stated above regarding infringement of claim 7, the Court will consider the merits of this motion despite Plaintiff's late addition of the claim 7 infringement claim.

[6] Medtronic apparently does not contend claim 7 is invalid for indefiniteness, which it asserted with respect to claim 5. The arguments the Court previously considered as to indefiniteness of claim 5 do not apply to claim 7 because claim 7 does not have the "longitudinal axis" language found in claim 5. (*See* Aug. 19, 2004 Order at 8-9.)

The Court considered and rejected these arguments in the August 19, 2004 Order. (*See* Order at 6-7.) The Court found there was no motivation to combine the Puno '602 and Webb '644 patents because prior art did not disclose the problem solved by the '555 Patent. Medtronic argues the Marnay '913 patent shows it was within the knowledge of those of ordinary skill in the art to modify the Puno '602 patent, but it does not contend the Marnay '913 patent identifies the problem to be solved. The Court adheres to its previous conclusion there is no motivation to combine the Puno '602 and Webb '644 patents.

Medtronic has not identified any difference between claim 5 and claim 7 requiring a different invalidity analysis for the claims. In fact, Medtronic apparently recognizes the issues are the same for both claims. Asserting this Court's August 19, 2004 ruling "was erroneous," Medtronic asks the Court to "look at this issue anew with respect to Claim 7." (Medtronic's Opp'n at 2 n. 2, 1.) Medtronic admits "the prior art of record is equally applicable to Claim 7 as it is as to Claim 5." (Medtronic's Opp'n at 2.) Also, "[c]laim 7 is invalid and unenforceable *for the very same reasons* that claim 5 is invalid and unenforceable." (Medtronic's Opp'n at 4 (emphasis added).) And, to support its position, "Medtronic expressly incorporates ... those same arguments, exhibits, and papers previously submitted to this Court." (Medtronic's Opp'n at 5.)

Having already decided all issues raised by Medtronic with respect to validity of both claim 5 and claim 7 of the '555 Patent, Plaintiff's motion for partial summary judgment of validity of claim 7 is GRANTED.

The title of Plaintiff's motion states it also seeks partial summary judgment on Medtronic's other affirmative defenses. Plaintiff's briefs, however, do not address the other affirmative defenses, including no infringement, no willful infringement, and failure to state a claim. Plaintiff has not met its burden of showing there is no genuine issue

of material fact as to these affirmative defenses. *See Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Plaintiff's motion is DENIED as to Medtronic's affirmative defenses other than invalidity.

III. *DISPOSITION*

Plaintiff's motion for partial summary judgment of infringement of claim 5 of the '555 Patent by Medtronic's new screw design is GRANTED. Medtronic's cross-motion for partial summary judgment of no infringement of claim 5 of the '555 Patent by Medtronic's new screw design is DENIED.

Plaintiff's motion for partial summary judgment of infringement of claim 7 of the '555 Patent by Medtronic's old and new screw designs is DENIED. Medtronic's cross-motion for partial summary judgment of no infringement of claim 7 of the '555 Patent by its old and new screw designs is GRANTED.

Plaintiff's motion for partial summary judgment on Medtronic's affirmative defense of invalidity, counterclaim of invalidity, and other affirmative defenses for claim 7 of the '555 Patent is GRANTED IN PART as to the affirmative defense and counterclaim of invalidity, and DENIED IN PART as to Medtronic's other affirmative defenses.

UNITED STATES COURT OF APPEALS,
FOR THE FEDERAL CIRCUIT

CROSS MEDICAL PRODUCTS, INC., Plaintiff–Appellee,

v.

MEDTRONIC SOFAMOR DANEK, INC. and Medtronic Sofamor Danek USA, Inc., Defendants–Appellants.

No. 05-1043

Sept. 30, 2005.
Rehearing and Rehearing En Banc
Denied Nov. 8, 2005.

---

424 F.3d 1293

Before SCHALL, GAJARSA, and LINN, Circuit Judges.

LINN, Circuit Judge.

Medtronic Sofamor Danek, Inc. et al. ("Medtronic") appeals from an order of the United States District Court for the Central District of California ("district court") permanently enjoining Medtronic from infringing claim 5 of U.S. Patent No. 5,474,555 ("the '555 patent") owned by Cross Medical Products, Inc. ("Cross Medical"). *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. SA CV 03-110-GLT(ANx) (C.D.Cal. Sept. 28, 2004). The permanent injunction was issued following the grant of Cross Medical's motions for partial summary judgment of

validity and infringement. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. SA CV 03-110-GLT(ANx) (C.D.Cal. Aug. 19, 2004) ("*Invalidity Opinion*"); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, No. SA CV 03-110-GLT(ANx) (C.D.Cal. May 20, 2004) ("*Infringement Opinion*"). As a threshold matter, we conclude, over Cross Medical's objection, that we have jurisdiction over this appeal. On Medtronic's challenge to the district court's claim construction rulings, we affirm the district court's construction of the "anchoring means," "securing means," and "bear against said channel" limitations, but modify the district court's construction of the "anchor seat means" and "operatively joined" limitations. Because we find genuine issues of material fact regarding infringement, we reverse the grant of Cross Medical's motion for partial summary judgment of infringement and find no abuse of discretion in the denial of Medtronic's cross-motion for partial summary judgment of non-infringement. We also reverse the grant of Cross Medical's motion for partial summary judgment that claim 5 is not obvious but affirm the grant of that motion as to indefiniteness and anticipation. We further conclude that the district court did not abuse its discretion in denying Medtronic's cross-motion for summary judgment as to these invalidity issues. Consequently, we vacate the permanent injunction. Thus, we affirm-in-part, reverse-in-part, vacate-in-part, and remand.

I. BACKGROUND

This appeal involves orthopedic surgical implants used to stabilize and align the bones of a patient's spine. A common problem with spinal fixation is determining how to secure the fixation device to the spine without damaging the spinal cord. Methods of fixation have developed which utilize wires that extend through the spinal canal and hold a

rod against the lamina,[1] or that utilize pedicular screws which extend into the pedicle[2] and secure a plate which extends across vertebral segments. The system taught in U.S. Patent No. 4,805,602 ("the '602 patent"), which is also assigned to Cross Medical and is part of the case against Medtronic but not involved in this appeal, exemplifies the advantages of both methods. The screw and rod system of the '602 patent provides a rigidity which is intermediate between wired implant and plate systems. Several screw and rod systems are known in the art. Those which feature an anchor secured to the bone by a separate screw are termed "polyaxial." Polyaxial screws have a capability of pivoting in the anchor. Devices in which the anchor and the bone screw form a unitary body are deemed "monoaxial." Monoaxial screws have no ability to pivot relative to the anchor.

Cross Medical's '555 patent discloses a device, an embodiment of which is illustrated in Figures 1, 2, and 3 below:

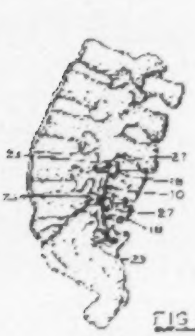


FIG - 1

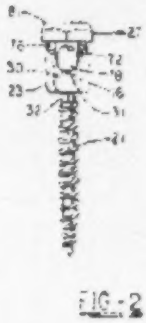


FIG - 2

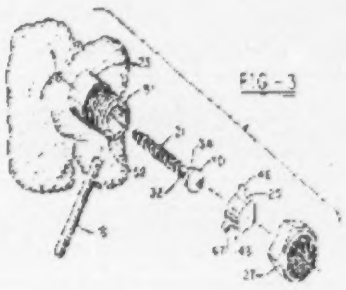


FIG - 3

The '555 device allows a surgeon to place a series of bone screws 21, each carrying an anchor seat 23, into the bones of a patient. A stabilization rod 18 thereafter may be

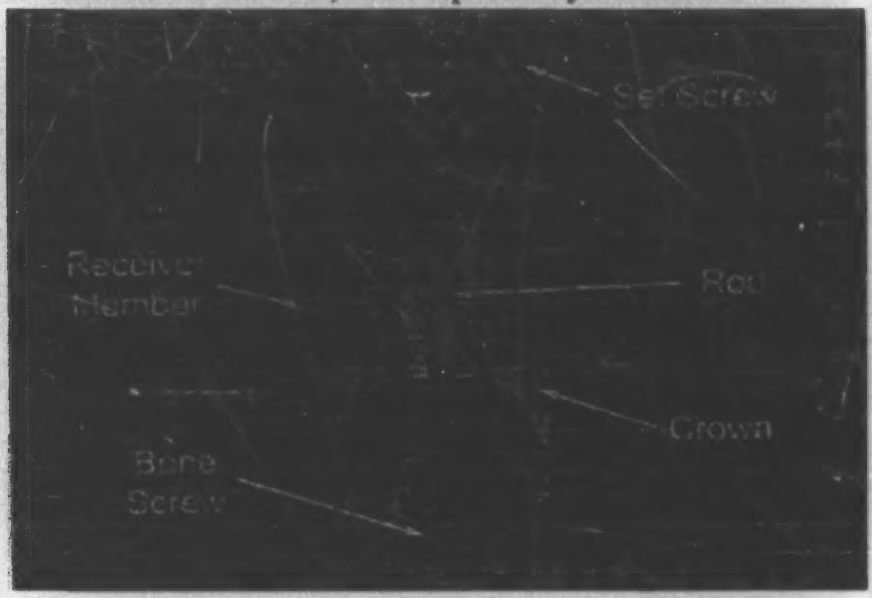
---

[1] The "lamina" is part of the neural arch of a vertebra extending from the pedicle to the median line.

[2] The "pedicle" is the basal part of each side of the neural arch of a vertebra connecting the laminae with the centrum.

positioned in the channels 51, 52 of the anchor seats. The '555 device allows surgeons to secure the rod to the anchor seats with top-tightening nuts 27. By connecting the rod in this fashion to the anchors on adjacent spinal bones, the position of the patient's spine may be fixed as desired by the surgeon.

On February 4, 2003, Cross Medical filed suit alleging that certain of Medtronic's polyaxial screws-MAS, Vertex, M8, Sextant, M10, Legacy 4.5, and Legacy 5.5—infringe the '555 patent and U.S. Patent No. 5,466,237 ("the '237 patent"). The accused devices employ a "set screw," which features external threads to mate with the receiver member's internal threads, to hold the rod in the receiver member. The accused devices also include a "crown member" that lies between the rod and the bone screw. An illustration of the accused device follows, with explanatory text added.



Medtronic denied infringement and counterclaimed seeking a declaratory judgment of non-infringement and invalidity. Subsequent to the initial pleading, responses and amended pleadings added claims and counterclaims relating to several additional patents, including the '602 patent. The district court resolved several issues through summary

adjudication. Of importance to this appeal, the district court separately entertained motions for partial summary judgment of infringement and validity of claim 5 of the '555 patent. Claim 5 recites:

A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:

> at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis, said anchors each comprising *anchoring means* which secure said anchors to said bone segment and an *anchor seat means* which has a lower bone interface *operatively joined* to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod; and
>
> *securing means* which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to *bear against said channel* through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8, ll. 33–57 (emphases added).

On May 29, 2004, the district court construed the "operatively joined," "securing means," and "bear against said channel" limitations of claim 5 of the '555 patent. Based on these constructions, the court granted Cross Medical's motion for partial summary judgment of

infringement, and denied Medtronic's cross-motion for partial summary judgment of non-infringement. On August 19, 2004, the district court additionally construed the "anchor seat means" and "anchoring means" limitations of claim 5 of the '555 patent. The court then denied Medtronic's motion for partial summary judgment that claim 5 was anticipated, obvious, and indefinite, and granted Cross Medical's cross-motion for partial summary judgment that claim 5 was neither anticipated, obvious, nor indefinite.

On September 28, 2004, with proceedings still on-going with respect to the '555 patent and other patents-in-suit, the district court granted Cross Medical's motion for a permanent injunction to preclude Medtronic's infringement of claim 5 of the '555 patent. The district court presumed irreparable harm because Cross Medical had prevailed on the merits at the summary judgment stage. Medtronic argued that there could be no harm because it withdrew all of the asserted infringing devices from the market; however, the district court found that some of the infringing products remained available and that Medtronic had the capacity to bring infringing product back to market. On October 4, 2004, the district court stayed the injunction for 90 days to allow Medtronic time to appeal.

On October 13, 2004, Medtronic appealed from the order granting the injunction, asserting jurisdiction under 28 U.S.C. § 1292(a)(1), (c)(1). Medtronic asks this court to review the district court's claim construction rulings, reverse or vacate the district court's partial summary judgment orders on infringement, indefiniteness, anticipation, and obviousness with respect to claim 5 of the '555 patent, and vacate the permanent injunction. On November 19, 2004, Cross Medical filed a motion to dismiss this appeal for lack of jurisdiction.

II. DISCUSSION

A. Jurisdiction

"Whether this court has jurisdiction over an appeal taken from a district court judgment is a question of law which we address in the first instance." *Pause Tech. LLC v. TiVo Inc.*, 401 F.3d 1290, 1292 (Fed.Cir.2005). Section 1292(a)(1) provides that the court of appeals has jurisdiction over appeals from interlocutory orders "granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions." 28 U.S.C. § 1292(a)(1) (2000). Section 1292(c)(1) provides this court exclusive jurisdiction over an appeal of an interlocutory order granting an injunction if we would otherwise have jurisdiction under § 1295. *Id.* § 1292(c)(1). Medtronic appeals from an order permanently enjoining Medtronic from infringing the '555 patent. On its face, the order falls within the scope of § 1292(a)(1), (c)(1).

Cross Medical argues that under *Woodard v. Sage Products, Inc.*, 818 F.2d 841 (Fed.Cir.1987) (en banc), this court does not possess jurisdiction because the injunction is one in form but not substance. Cross Medical asserts that the injunction is not coercive because it enjoins Medtronic from engaging in activities it had abandoned before the injunction issued. Cross Medical asserts that Medtronic simply should have sought a stay of the injunction pending appeal under Federal Rule of Appellate Procedure 8(a). Alternatively, Cross Medical argues that even if the court has jurisdiction to review the order, it has no jurisdiction to reverse or vacate the partial summary judgment rulings because no final judgment on the '555 patent has been entered, and the orders were not certified for appeal.

Medtronic counters that the order falls under § 1292(a)(1), (c)(1). Medtronic asserts that *Sage Products* is inapposite and that no case has denied jurisdiction in an appeal from the grant of an injunction. Medtronic states that Cross Medical argued below that the injunction was

necessary to prevent irreparable harm, that Medtronic pulled products from the market to avoid a willfulness finding, that the district court entered the injunction with full knowledge of Medtronic's actions, and that it would be unfair to deny Medtronic its statutory right of appeal.

Cross Medical's reliance on *Sage Products* is misplaced. In *Sage Products*, plaintiff's amended complaint included a prayer for injunctive relief, and the issue was whether plaintiff could lodge an appeal under § 1292(a)(1) from an order granting defendant's motion for summary judgment of non-infringement. 818 F.2d at 843–44. There was no order specifically denying injunctive relief. *Id.* Instead, plaintiff argued that the adverse summary judgment ruling had the effect of denying injunctive relief. *Id.* at 844. This court sitting en banc considered the impact of the Supreme Court's then recent decision in *Carson v. American Brands, Inc.*, 450 U.S. 79, 101 S.Ct. 993, 67 L.Ed.2d 59 (1981). We explained that *Carson* "instructed that an interlocutory appeal under section 1292(a)(1) requires (a) that the order be injunctive in nature, (b) that it cause a serious, if not irreparable, consequence, and (c) that the order can be effectively challenged only by immediate appeal." *Sage Products*, 818 F.2d at 849. We held that Woodard failed to establish that the order met the *Carson* requirements. *Id.* at 855.

However, in reporting on how other courts interpreted *Carson*, we criticized the Seventh Circuit for applying "the *Carson* requirements to an order *explicitly* granting an injunction," observing that "the Supreme Court in *Carson* expressly limited its holding to orders that have 'the practical effect of refusing an injunction.'" *Id.* at 850 n. 6 (quoting *Carson*, 450 U.S. at 84, 101 S.Ct. 993). We explained that "as a rule of general applicability to orders deemed to deny injunctions, the *Carson* rule is workable and sensibly balances the statutory provisions of sections 1291 and 1292(a)(1) in light of their respective purposes." *Id.* at 853. The Supreme Court subsequently confirmed our reading of

Carson as applying only to orders that have "the practical effect of granting or denying injunctions." *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 287-88, 108 S.Ct. 1133, 99 L.Ed.2d 296 (1988) ("Section 1292(a)(1) will, of course, continue to provide appellate jurisdiction over orders that grant or deny injunctions and orders that have the practical effect of granting or denying injunctions and have '"serious, perhaps irreparable, consequence."'" (quoting *Carson*, 450 U.S. at 84, 101 S.Ct. 993 (quoting *Baltimore Contractors v. Bodinger*, 348 U.S. 176, 181, 75 S.Ct. 249, 99 L.Ed. 233 (1955)))); *see also* 19 James Wm. Moore et al., *Moore's Federal Practice* ¶ 203.10[2][a], at 12 (3d ed. 2005) ("*Moore's*") ("While the statute clearly applies to orders that formally grant injunctive relief, it also authorizes interlocutory appeals from orders that have the practical effect of granting an injunction."). Therefore, "if the district court's order expressly grants an injunction, the order is appealable under § 1292(a)(1), without regard to whether the appellant is able to demonstrate serious or irreparable consequences." *Moore's* ¶ 203.10[2][a], at 14.

In this case, the district court entered an order expressly enjoining Medtronic from infringing claim 5 of the '555 patent. Thus, *Carson* is inapplicable. *See PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1242 (Fed.Cir.2002) (finding jurisdiction without referring to the *Carson* test because "[t]he district court's grant of a permanent injunction ... [brought the] appeal squarely within the confines of § 1292(a)(1)"). On appeal from the district court's grant of the injunction, we have jurisdiction under 28 U.S.C. § 1292(a)(1).

Moreover, we may review the underlying partial summary judgment orders because they are inseparably connected to the merits of the permanent injunction. *See id.* at 1242–48 (reviewing a summary judgment ruling that a claim was not anticipated by the prior art where jurisdiction

was based on § 1292(a)(1), (c)(1)); *Katz v. Lear Siegler, Inc.*, 909 F.2d 1459, 1461 (Fed.Cir.1990) (reviewing propriety of joinder of counter-defendant on appeal from injunction); *Moore's* ¶ 203.10[7][b], at 45–47 ("[An interlocutory appeal under § 1292(a)(1)] enable[s] the circuit court to review other orders that are inseparably or very closely connected with the merits of the injunctive order ...."). The district court presumed irreparable harm based on Cross Medical's success on the merits, which manifested itself in the summary judgment orders concerning claim 5. Because Cross Medical's success on the merits turns on the propriety of the summary judgment rulings, our review of the grant of the permanent injunction requires that we rule on the summary judgment orders. *See Mendenhall v. Barber–Greene Co.*, 26 F.3d 1573, 1581 n. 12 (Fed.Cir.1994) (noting "that an interlocutory appeal from a permanent injunction, to the extent that it considers questions of validity and infringement ... is *identical* in substance to an appeal brought under § 1292(c)(2)"). The cases cited by Cross Medical are not germane.

For these reasons, Cross Medical's motion to dismiss the appeal for lack of jurisdiction is denied.

B. Standard of Review

"We review the grant of a permanent injunction for an abuse of discretion which requires plenary review of the correctness of ... rulings on matters of law." *Stratos Mobile Networks USA, LLC v. United States*, 213 F.3d 1375, 1379 (Fed.Cir.2000) (internal quotations omitted). We review the grant of a motion for summary judgment *de novo*. *Id.* However, we review the denial of a motion for summary judgment for abuse of discretion. *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1338 (Fed.Cir.2001). Summary judgment should only be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a

judgment as a matter of law." Fed.R.Civ.P. 56(c). In applying this standard, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [the non-movant's] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). "The fact that both the parties have moved for summary judgment does not mean that the court must grant summary judgment to one party or the other.... Cross-motions are no more than a claim by each party that it alone is entitled to summary judgment, and the court must evaluate each motion on its own merits, taking care in each instance to view the evidence in favor of the nonmoving party." *Bubble Room, Inc. v. United States*, 159 F.3d 553, 561 (Fed.Cir.1998) (internal citation omitted); *accord Gart*, 254 F.3d at 1338-39.

Claim construction is a question of law reviewed *de novo*. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1328 (Fed.Cir.2005) (en banc). Determination of infringement is a factual question. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998). "Indefiniteness, ... like claim construction, is a question of law that we review *de novo*." *Atmel Corp. v. Info. Storage Devices*, 198 F.3d 1374, 1378 (Fed.Cir.1999). Anticipation is a question of fact. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1281 (Fed.Cir.2000). "Obviousness is a question of law based on underlying facts." *Group One Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1303 (Fed.Cir.2005).

C. Claim Construction

In the course of its rulings on partial summary judgment for both infringement and validity, the district court construed the "anchoring means," "anchor seat means," "operatively joined," "securing means," and "bear against said channel" limitations of claim 5. Medtronic challenges each construction.

1. "*anchors each comprising anchoring means ... and anchor seat means*"

In the district court, the parties disputed whether either the "anchoring means" limitation or "anchor seat means" limitation imposed a requirement that the bone screws be polyaxial. The district court did not construe each limitation separately. Instead, the district court referred to its prior ruling in *Cross Medical Products, Inc. v. DePuy AcroMed, Inc.*, No. SA CV 00-876-GLT(ANx), (C.D.Cal. Jan. 9, 2003), and explained that both the "anchoring means" and "anchor seat means" limitations were in § 112, ¶ 6 form and "must be construed by referring to the specification." *Invalidity Opinion* at 3–4. The district court held that "although the claim language itself does not indicate whether the screws are polyaxial or monoaxial, the specifications and the drawings establish that the claims are limited to polyaxial screws." *Id.* at 3.

Medtronic asserts that although the preferred embodiment describes a polyaxial screw, there is no basis to read this feature into claim 5 because neither "anchoring means" nor "anchor seat means" are § 112, ¶ 6 limitations. Medtronic argues that even if these are § 112, ¶ 6 limitations, a monoaxial screw is an alternative embodiment and, thus, should be considered corresponding structure, citing *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 194 F.3d 1250 (Fed.Cir.1999). Medtronic also relies on the doctrine of claim differentiation, arguing that the recitation in claim 1 of a polyaxial screw limitation implies that claim 5 does not possess that limitation. Finally, Medtronic adds that Cross Medical is estopped from denying that claim 5 covers monoaxial screws because Cross Medical marked its monoaxial screws with the '555 patent number.

Cross Medical counters that both "anchoring means" and "anchor seat means" are § 112, ¶ 6 limitations and their corresponding structure is a polyaxial screw. Cross Medical argues that claim differentiation must give way to a proper

§ 112, ¶ 6 analysis and that the court should not consider "marking estoppel" in construing claim 5 because marking is extrinsic evidence. Cross Medical adds that claims should be construed to preserve their validity.

The limitations at issue are contained in the following text of claim 5:

> said anchors each compris[e] *anchoring means* which secure said anchors to said bone segment and an *anchor seat means* which has a lower bone interface operatively joined to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod....
>
> ... said *seat means* including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel ....

'555 patent, col. 8, ll. 36–43, 46–51 (emphases added).

a. "anchoring means"

The limitation recites the word "means," which gives rise to the presumption that § 112, ¶ 6 applies. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed.Cir.1999). The claimed function of the "anchoring means" is to "secure said anchors to said bone segment." '555 patent, col. 8, ll. 38–39. No structure is recited in the claim to perform this function. *See id.*, ll. 35–56. Thus, § 112, ¶ 6 applies and the "claim shall be construed to cover the corresponding structure ... described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2000); *Al–Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1320 (Fed.Cir.1999).

The specification discloses only one embodiment. That embodiment contains a screw which carries a separate anchor such that "when the screw 21 engages the anchor seat 23, a limited ball-and-socket joint is formed which permits

freedom of movement between the rod support 23 and the screw 21." '555 patent, col. 5, ll. 4–47. The specification unambiguously states that a feature of the "present invention" is that "[e]ach anchor seat is secured by a cancellous screw which cooperates through a sloped bore in the anchor seat so as to provide a limited ball and socket motion." *Id.*, col. 1, l. 65–col. 2, l. 21. It continues:

> The present invention utilizes a rod and vertebral anchors which holds [sic] the rod in position. Each anchor is secured to the vertebrae by a transpedicular screw member.
>
> ....
>
> ... [T]he present design utilizes two implant sets on either side of the spinous processes. Each implant set includes a ... rod .... Generally, an implant set is used on each side of the spinous process .... The rod is held in position by a stainless steel vertebral anchor which captures the rods. *The anchor has a seat member which is secured to the vertebrae by a stainless steel transpedicular screw. The screw is separate from the anchor seat and thus provides for limited motion between the anchor seat and the vertebrae.*

Id., col. 3, ll. 26–67 (emphasis added). The patent discloses no other structure for securing the anchor to the bone. The patent states that the polyaxial design "acts as a 'shock-absorber' to prevent direct transfer of load from the rod to the bone-screw interface prior to achieving bony fusion, thereby decreasing the chance of failure." *Id.*, ll. 63–67. Thus, the district court was correct both in linking the recited function to the structure disclosed in the specification and in concluding that the corresponding structure was polyaxial. Medtronic argues that even if the limitation is a means-plus-function limitation linked to the disclosed polyaxial structure, the claim nonetheless should be construed to include alternative structures like monoaxial screws.

However, because there is only one embodiment described in the specification to secure the anchor to the bone—a polyaxial screw and anchor structure—there is no basis on which to extend the limitation to cover alternative, non-disclosed structure not shown to be structurally equivalent. *See* 35 U.S.C. § 112, ¶ 6; *Al-Site*, 174 F.3d at 1320.

We reject the parties' remaining arguments. First, although the doctrine of claim differentiation suggests that claim 5 should be broader than claim 1, any presumption that the claims differ with respect to this feature may be overcome by a contrary construction mandated by the application of § 112, ¶ 6. *See Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed.Cir.1991) (holding that the doctrine of claim differentiation yields to an interpretation mandated by § 112, ¶ 6). Second, Medtronic's assertion that "marking estoppel" applies is incorrect. Even if Cross Medical marked monoaxial screws with the '555 patent number, such evidence conflicts with the intrinsic record and has no bearing on our construction. *See Phillips*, 415 F.3d at 1318 ("[A] court should discount [extrinsic evidence] that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." (internal quotation omitted)); *cf. SmithKline Diagnostics v. Helena Labs. Corp.*, 859 F.2d 878, 890–91 (Fed.Cir.1988) (holding that an accused infringer's mis-marking of a product could not convert by estoppel an admittedly non-infringing product into an infringing product). Finally, Cross Medical's argument that we should consider the validity of claim 5 in construing the limitation misses the mark. Because the other claim construction tools unambiguously resolve the claim construction dispute, considering validity would be improper. *Phillips*, 415 F.3d at 1327 ("[W]e have limited the maxim [of construing a claim to preserve its validity] to cases in which 'the court

concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'").

b. "anchor seat means"

While the limitation recites the word "means," thus giving rise to the presumption that § 112, ¶ 6 applies, *see Rodime*, 174 F.3d at 1302, the claim language is sufficiently structural as to take the limitation out of the ambit of § 112, ¶ 6. Thus, the district court erred in treating "anchor seat means" as a means-plus-function limitation; however, that error is harmless with respect to the conclusion that the claim covers polyaxial structures, based on the district court's correct construction of the "anchoring means" limitation, discussed *supra*.

2. *"operatively joined"*

The district court construed "lower bone interface operatively joined to said bone segment" to mean "connect[ed] during a surgical procedure." *Infringement Opinion* at 5. The district court interpreted "connect" to mean "in contact." *See id.* & n. 2. The district court reasoned that because the claim involves a surgical procedure, "operatively" means "involving surgical operations." *Id.* The district court explained that construing "operatively" to mean "to produce an appropriate effect" would improperly import a limitation from the specification. *Id.* at 4–5.

Medtronic argues that the "bone interface" language surrounding the phrase "operatively joined" requires that there be contact between the bone segment and the anchor seat. Medtronic asserts that "operatively" means to produce an effect and that effect is micro-motion, which Medtronic describes as "limited motion" between the anchor and the bone. Medtronic argues that it would be inconsistent to construe claim 5 to require a polyaxial screw which enables polyaxial movement, but not to require a micro-motion effect. Medtronic adds that the district court's construction

renders "op[illegible]vely" superfluous because the only way to attach the screw to bone is via surgery.

Cross Medical counters that the "bone interface" is the portion of the anchor seat that comes into contact with the bone when there is contact, but that "bone interface" does not require contact. Cross Medical argues that the district court correctly construed "operatively" to mean "surgically." Cross Medical asserts that even if we construe "operatively" to mean "effectively," the effect is posterior stabilization, not micro-motion. Cross Medical adds that "polyaxial" and "micro-motion" are not synonymous.

The claim recites an "anchor seat means which has a lower bone interface operatively joined to said bone segment." '555 patent, col. 8, ll. 39–42. The claim does not state explicitly whether the "bone interface" and the "bone segment" must be in contact. However, we may refer to the dictionary to begin understanding the ordinary meaning of these claim terms, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1322–23 (internal quotations omitted). "[B]one" modifies "interface," indicating that the anchor seat has a "lower" portion that may share a "common boundary" with "bone." *See Webster's Third New Int'l Dictionary* 1178 (2002) (defining "interface"). The term "joined" describes the relationship between the "bone interface" and the "bone segment." Use of the word "joined" indicates that the "interface" and the "bone" must be brought together or connected to form a single unit, a whole, or a continuity, and thus that the interface and the bone are in contact. *See id.* at 1218 (defining "join").

The written description confirms that the interface must contact the bone. The screw is separate from the anchor seat, which prevents the direct transfer of load from the rod to the "bone-screw interface," and decreases the chance of failure of the "bone-screw interface." *Id.*, col. 3, ll. 19–22, ll. 64–

67. This use of the term "interface" is consistent with its meaning a "common boundary" between two parts. Moreover, the patent refers to the "anchor" as being held, '555 patent, Abstract, or "secured" to the bone, *id.*, col. 3, ll. 59–60, and to the point of attachment as a "fusion bed," *id.*, col. 7, l. 15. These references suggest contact between the anchor seat and the bone. Furthermore, to adjust the height of the anchor posterior to the bone, the patent teaches the addition of washers that are the same diameter as the anchor seat. *Id.*, col. 5, ll. 50–57. The washers co-act with the anchor seat to function as the bone interface while elevating the seat. If contact with bone were not contemplated, then there would be little need to add washers to elevate the seat. The drawings show contact between the anchor and bone, which is consistent with the description. *Id.*, Figures 3, 14, 17–20. Because the ordinary meaning of "interface" and "joined," as reflected in dictionary definitions and in the overall context of the intrinsic record, leads to the conclusion that a person of ordinary skill in the art would have understood these terms to require "contact" between the interface and the bone, the district court's construction in this regard was correct. It would be improper to construe "joined" more broadly to mean "connected" without requiring contact.

As to "operatively," the term is often used descriptively in patent drafting to mean "effectively" in describing the functional relationship between claimed components. *See, e.g., Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1118 (Fed.Cir.2004) ("[Operatively connected] is a general descriptive term frequently used in patent drafting to reflect a functional relationship between claimed components."). Here, the preamble of the claim recites that the invention is operative when it effects posterior stabilization of one or more bone segments of the spine. '555 patent, col. 8, ll. 33–34; *see Innova*, 381 F.3d at 1118 (declining to decide whether preamble was an

affirmative limitation, but recognizing that preamble recited the intended use corresponding to "operatively"). The body of the claim is consistent as it calls for anchors and a stabilizer rod, and provides detail on how these structures interrelate to stabilize the bone segment. *See* '555 patent, col. 8, ll. 35–57; *Innova*, 381 F.3d at 1118–19 (looking to the body of the claim to understand the purpose). Although the written description does not define "operatively," it consistently describes the purpose of the device to be for posterior stabilization. *See* '555 patent, col. 1, ll. 9–12 ("This invention relates generally to an apparatus for immobilization of the spine, and more particularly, to an apparatus for posterior internal fixation of the spine ...."); *Innova*, 381 F.3d at 1118–19 (looking to the written description to understand the purpose). It discusses disadvantages of prior art spinal fixation methods and apparatuses, '555 patent, col. 1, ll. 13–64; col. 2, l. 36–col. 3, l. 25, details how the invention's features provide an advantageous fixation system, *id.*, col. 3, l. 26–col. 6, l. 44, and provides a method of spinal fixation therapy for use with the device, *id.*, col. 6, l. 45–col. 7, l. 50. Therefore, from the context of the written description, it is clear that one of ordinary skill in the art would have understood "operatively" to mean effective to produce posterior stabilization. The district court erred in construing "operatively" to mean "surgically." Because the only way a "fixation device" can provide "posterior stabilization" is through a surgical procedure, construing "operatively" to mean "surgically" renders the word superfluous, as used in the claim.

For all of these reasons, we modify the district court's claim construction and conclude that, in claim 5, the "lower bone interface [is] operatively joined to said bone segment" when the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization.

3. "*securing means*"

The district court considered the "securing means" limitation to be in § 112, ¶ 6 form, and described its function as "appl[ying] a force to the rod, which compresses the rod against the anchor seats and secures the rod in place." *Infringement Opinion* at 6. The district court explained that compression must be applied on "either side"—either inside or outside—of the rod-receiving channel. *Id.* at 7. The district court identified the corresponding structure as an "outer nut." *Id.* at 6.

Medtronic argues that the district court's interpretation of the function of the "securing means" somehow ignores the claim language: "through the application of substantially equal compressive forces ... *applied on either side along said longitudinal axis of said channel,*" '555 patent, col. 8, ll. 54–57 (emphasis added). Medtronic asserts that this language mandates that forces be applied along the longitudinal axis of the rod on "either side" of the channel and not on "either side" of the vertical axis. Medtronic interprets "either side" of the channel to be on the "outside" of the channel. Although Medtronic does not dispute that the corresponding structure is an external nut, Medtronic argues that the written description and prosecution history show a disavowal of equivalents to an external nut.

Cross Medical responds that the district court did not ignore the "either side" limitation, and that, in any event, "either side" can mean that the forces are applied "inside" the channel. Cross Medical provides the illustration that standing on "either side" of the room would connote standing inside the room. Cross Medical adds that the specification and prosecution history do not evince a disavowal, and that claim differentiation doctrine supports structural equivalents.

The claim requires:

> at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis ....
>
> securing means which cooperate with each of said anchor seat portions ... said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8, ll. 36–37, 44–57.

We agree with the parties that the limitation is in § 112, ¶ 6 format. *See Rodime*, 174 F.3d at 1302 (noting that a concession by the parties that the claim is in § 112, ¶ 6 form does not relieve the court of its duty to examine whether § 112, ¶ 6 applies). The claim recites "securing means," which gives rise to the presumption that § 112, ¶ 6 applies. *See id.* The function is "to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel." '555 patent, col. 8, ll. 53–57.

"[E]ither side" does not refer to "either side" of the rod on the vertical axis of the channel perpendicular to the rod, because that interpretation would render the "in the direction of the vertical axis" language redundant. The "and" in the phrase "in the direction of the vertical axis *and* applied on either side" makes that clear. Therefore, the function is to cause the rod to bear against the rod-receiving channel by applying a compressive force in the direction of the vertical axis while ensuring that substantially equal forces are applied along the longitudinal axis of the rod on opposite

sides—either inside or outside—of the rod-receiving channel.

We must now determine whether the claim recites structure to carry out that function. The claim states that the "securing means ... cooperate with each of said anchor seat portions," *id.*, ll. 44–45, in that the "securing means include[s] second threads which cooperate with the first threads of the seat means to cause [the desired function]," *id.*, ll. 51–57. Although it is the operation of the threads that causes the rod to bear against the channel by applying a compressive force in the direction of the vertical axis, a naked incantation of threads alone does not ensure that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides of the rod-receiving channel. Because there is insufficient structure recited for performing the specified function, § 112, ¶ 6 applies. Thus, we construe the claim "to cover the corresponding structure ... described in the specification and equivalents thereof."

The structure for performing the recited function is described as follows:

> The nut 27 includes internal threads 83 which engage the external threaded area 76 on the anchor seat. The nut 27 is a hex nut which can be tightened relative to the seat 25.
>
> As the nut 27 is rotated about the anchor seat 25, it cooperates with the top side of the flange 46,47 to tighten the clamp 25 in relation to the rod support 23. The rod 18 is grasped in the tunnel 84 formed between the rod-receiving channel 54 of the anchor seat 23 and the arch 72 of the cap 25.
>
> The threads 76 on the anchor seat 23 extend downwardly on the seat below the top of the cylindrical surface of the rod 18 as is shown in FIG. 2 and the nut 27 has a relatively constant diameter through the bore as is shown in FIGS. 2 and 4. Accordingly, the nut 27 can be screwed directly

> onto the anchor seat 23 to compressively hold the rod without the cap 25.

'555 patent, col. 6, ll. 9–24. Figures 5 and 7 depict the rod 18 in the channel created by the anchor seat 23, with the nut 27 securing the rod in place. Thus, the structure that corresponds to the claimed function is a nut with internal threads cooperating with the external threads of the anchor seat (an "external nut"). The claim covers that structure and equivalents thereof.

We are not persuaded by Medtronic's argument that the written description shows a disavowal of equivalents. Although we need not decide that there can never be a disavowal of § 112, ¶ 6 equivalents, " § 112-6 was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification." *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed.Cir.1985). In this case, the inventors were merely describing the structure that performs the claimed function.

Nor are we persuaded that the prosecution history shows a disavowal. In an August 4, 1994 Office Action ("*Office Action*"), the Examiner rejected the apparatus claims, in part, under § 112, ¶ 1, because "[t]he specification fail[ed] to provide an enabling description of the embodiment of the action device excluding the cap/cap means," and because "language directed toward the 'securing means' cooperating with the seat means through application of compressive forces by the securing means" failed to have support in the specification. *Office Action* at 4. Subsequent to that rejection, an interview was held with the Examiner and the Examiner Interview Summary referred to "securing means" as "i.e., the nut." In addition, Remarks in the April 27, 1995 Amendment ("*Amendment*") stated that Applicant amended the claims "to define the anchor seat means having a channel and threads which cooperate with the securing means (i.e., the nut) so as to capture the stabilizer between the channel

and the securing means." *Amendment* at 4. However, Applicant did not add language in claim 5 that limited securing means to a nut. The statements referring to "securing means" as "i.e., the nut" simply help to provide the requisite linkage between the function recited in the claim and the "corresponding" structure. *See Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed.Cir.2005) ("A structure disclosed in the specification qualifies as "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim."). Applicant did not disclaim all structural equivalents.

Therefore, the district court correctly construed the "securing means" limitation to refer to the external nut described in the written description. Under § 112, ¶ 6, the claim also covers equivalents thereof.

4. "*bear against said channel*"

The parties dispute whether the language of claim 5 reciting that the "rod ... bear[s] against said channel" precludes the presence of any intervening structure between the rod and the channel. The district court held that "[t]here is nothing in the [language of claim 5] which excludes an anchor channel composed of more than one component part." *Infringement Opinion* at 8. Medtronic argues that the district court's construction is erroneous, and that by placing a separable crown member over the anchor seat, Medtronic has prevented the rod from "bear[ing] against [the] channel" as a matter of law. Medtronic asserts that the anchor seat must form the channel and the crown is not part of the anchor seat. Cross Medical responds that claim 5 does not require that the channel of the anchor seat be a unitary component and thus does not preclude a finding that the crown is part of the anchor seat.

The dispute reduces to whether the "channel" must be formed in a unitary structure. The claim requires that the

anchor seat means have "an anchor seat portion spaced apart from said bone interface including a channel to receive said rod," '555 patent, col. 8, ll. 41–42, and that the "securing means ... cause[s] said rod to bear against said channel," *id.*, ll. 51–54. The claim does not state that the anchor seat portion forming the channel is unitary. Although the sole embodiment described in the specification depicts a unitary structure, *id.*, col. 5, ll. 20–21, the mere depiction of a structural claim feature as unitary in an embodiment, without more, does not mandate that the structural limitation be unitary. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1367 (Fed.Cir.2002) (holding that "member" encompassed a multi-component structure where the preferred embodiment showed a single-component structure, but the specification did not otherwise require a certain number of components). There is nothing in the written description or prosecution history that limits the channel to being formed in a single-component structure. Thus, the district court correctly concluded that the "bear against said channel" language of claim 5 does not exclude an "anchor seat portion" composed of multiple components.

D. Infringement

The district court ruled as a matter of law that the accused devices met the "operatively joined," "securing means," and "bear against said channel" limitations, that Medtronic was a direct infringer, and that alternatively, Medtronic either contributed to infringement or induced infringement. *Infringement Opinion* at 4–9. Medtronic appeals.

1. *"operatively joined"*

The district court held that the accused devices met the "operatively joined" limitation as a matter of law because "the accused device, to be infringing, need only be capable of operating in the [infringing] mode ... actual [infringing] operation in the accused device is not required." *Id.* at 5–6 (quoting *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d

821, 832 (Fed.Cir.1991)). The district court cited *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed.Cir.2001), for the proposition that "an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." *Infringement Opinion* at 5. The court explained that Medtronic's devices "are capable of operative joinder to the bone segment, and are sometimes used in this way." *Id.* at 5–6. In response to Medtronic's argument that it could not directly infringe because it did not perform surgery, the district court held that "under 35 U.S.C. § 271 Defendants can be liable for inducing the infringement or for selling a device which constitutes part of the invention." *Id.* at 8.

Medtronic argues that it does not itself make an anchor seat which contacts bone and it does not perform surgery. Medtronic asserts that *Intel* and *Hilgraeve* are inapposite and that it cannot be a direct infringer simply because its accused devices are capable of being made into infringing devices by surgeons. Medtronic adds that it does not induce or contribute to infringement because there is no evidence of physicians bringing the receiver member into contact with the bone segment to make the claimed apparatus; because Medtronic does not design the receiver member to contact the bone segment; and because Medtronic instructs surgeons not to place the device into contact with the bone.

Cross Medical counters that to directly infringe, Medtronic need only make devices that are capable of being converted into infringing devices, citing *Intel, Hilgraeve*, and *Bell Com. Research Inc. v. Vitalink Com. Corp.*, 55 F.3d 615 (Fed.Cir.1995). Cross Medical asserts that Medtronic's argument that it does not directly infringe because it does not perform surgery is as superficial as the non-infringement argument concerning the "Commissioner.com" product in *Fantasy Sports Props., Inc. v. SportsLine.com, Inc.*, 287 F.3d 1108 (Fed.Cir.2002), and therefore must fail. Furthermore,

Cross Medical argues that Medtronic's representatives are present in the operating room and thus that Medtronic performs surgery. Alternatively, Cross Medical argues that Medtronic induces infringement because it sells devices to surgeons, designs its anchors to function when in contact with bone, and intends that surgeons bring the anchor seat into contact with bone; and because surgeons actually bring the anchor seat into contact with bone. Cross Medical asserts that Medtronic is a contributory infringer because it has not proven that there are substantial non-infringing uses.

"[W]hoever without authorization makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor [directly] infringes the patent." 35 U.S.C. § 271(a) (2000). To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed.Cir.2001). "Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." *Franks Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed.Cir.2004) (internal citation omitted). Claim 5 of the '555 patent is an apparatus claim. *See* '555 patent, col. 8, ll. 34–57. We held in Part II.C.2 *supra* that the "operatively joined" limitation requires that "the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization."

In support of its argument that Medtronic directly infringes, Cross Medical cites evidence that Medtronic's representatives appear in the operating room, identify instruments used by surgeons, and thus in effect "join" the anchor seat to the bone. Cross Medical argues that the situation is analogous to those in which courts have found a party to directly infringe a method claim when a step of the

claim is performed at the direction of, but not by, that party. *See, e.g., Shields v. Halliburton Co.*, 493 F.Supp. 1376, 1389 (W.D.La.1980). However, if anyone makes the claimed apparatus, it is the surgeons, who are, as far as we can tell, not agents of Medtronic. Because Medtronic does not itself make an apparatus with the "interface" portion in contact with bone, Medtronic does not directly infringe.

Nor does *Intel* support a finding of direct infringement. The claim at issue in *Intel* called for a "programmable selection means" and thus required only that an accused device be capable of operating in the enumerated mode. 946 F.2d at 832; *see Fantasy Sports*, 287 F.3d at 1117–18; *High Tech Med. Instrumentation Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555–56 (Fed.Cir.1995). Here, the claim does not require that the interface be merely "capable" of contacting bone; the claim has a structural limitation that the anchor seat be in contact with bone. *See Fantasy Sports*, 287 F.3d at 1117–18 (stressing the "programmable" language of the claim at issue in *Intel* and holding that *Intel* "does not stand for the proposition ... that infringement may be based upon a finding that an accused product is merely capable of being modified in a manner that infringes the claims of a patent"); *High Tech*, 49 F.3d at 1555–56 (distinguishing *Intel* based on the permissive language of the claim at issue). Cross Medical would distinguish *High Tech* by asserting that the device in that case had to be physically altered to become infringing, while Medtronic's device need not be altered. However, Cross Medical again fails to recognize that the limitation—the anchor seat being in contact with bone—is absent until the screw and anchor are put in place during surgery.

Bell Communications and *Hilgraeve* are also inapposite. In *Bell Communications*, plaintiff asserted that defendant's product embodied a claimed method, but the district court granted summary judgment of non-infringement reasoning that the product had non-infringing modes of operation. 55

F.3d at 618–19. In *Hilgraeve*, plaintiff asserted that defendant sold software that, when in operation, infringed plaintiff's method claim, but the district court granted summary judgment of non-infringement based on rationale similar to that in *Bell Communications*. *See Hilgraeve*, 265 F.3d at 1339–40. In both cases on appeal, this court held that the district court had erred by overlooking the rule that "an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes." *Bell*, 55 F.3d at 622–23; *accord Hilgraeve*, 265 F.3d at 1343 ("[S]o too the sale of a device may induce infringement of a method claim even if the accused device is capable of non-infringing modes of operation in unusual circumstances."). However, a rule that governs infringement of a method claim may not always govern infringement of an apparatus claim. *See, e.g., NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317–18 (Fed.Cir.2005) (distinguishing between method claims and apparatus claims for the purpose of determining infringement under section 271(a)). To infringe an apparatus claim, the device must meet all of the structural limitations. *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed.Cir.1990) ("[A]pparatus claims cover what a device *is*, not what a device *does*."); *In re Michlin*, 45 C.C.P.A. 1028, 256 F.2d 317, 320 (1958) ("It is well settled that patentability of apparatus claims must depend upon structural limitations and not upon statements of function."). In this case, claim 5 is an apparatus claim which contains the structural limitation that the anchor seat contact bone. Cross Medical has not proven that Medtronic makes an apparatus with an anchor seat in contact with bone.

Cross Medical's reliance on *Fantasy Sports* is also misplaced. In *Fantasy Sports*, the apparatus claim called for "[a] computer for playing football." 287 F.3d at 1111. The district court found that the accused "Commissioner.com" product did not infringe because it was a "modifiable software tool," not a computer for playing football. *See id.*

at 1118. We disagreed, holding that Sportsline directly infringed by making or using the apparatus because no reasonable juror could find that the "Commissioner.com" product was not software installed on a computer. *See id.* at 1118–19. Cross Medical argues that the theory that Medtronic does not directly infringe because it does not itself contact the anchor seat to the bone is as superficial as Sportsline's theory that its product was software but not a computer. However, unlike in *Fantasy Sports*, in this case, no reasonable juror could find that the accused infringer itself makes or uses the entire claimed apparatus. The anchor seat of the device does not contact bone until the surgeon implants it.

Because Medtronic is not a direct infringer, we next consider whether Medtronic induces or contributes to infringement. Under § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "'In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement,' and 'second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.'" *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed.Cir.2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed.Cir.2002)). Under § 271(c), "[w]hoever offers to sell or sells within the United States ... a component of a patented machine, manufacture, combination or composition ... constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(b). In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, plaintiff must show that defendant

"knew that the combination for which its components were especially made was both patented and infringing" and that defendant's components have "no substantial non-infringing uses." *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed.Cir.2004) (internal quotations omitted).

As to the predicate act of direct infringement, we conclude that there is a genuine issue of material fact as to whether surgeons infringe by making the claimed apparatus. The only evidence that Cross Medical cites suggesting that the anchor seat contacts bone is the statement of Medtronic's employee, Michael Sherman, during his January 29, 2004 deposition:

> Q. How far down do you screw the screw initially?
>
> A. Well, it depends. Because if you screw these screws all the way down, they stop rotating. And the rotating around the ball is a feature of the screw. So you lose some of your ability to rotate, or your freedom.
>
> Because the reason these screws have multiple angles is to make it easier to assemble the system in the patient. So if you screw these things down super-tight, you may have—you know, you've eliminated the multiaxial capability of the screw.
>
> So the surgeon in his judgment gets it down, and I like to tell them, as far as they feel comfortable doing and still have some rotation. Because the further in the instrumentation is into the patient, the lower—the closer the instrumentation is to the loads, and thus the lower the bending moments are on the instrumentation and the less likelihood of metal failure.
>
> Q. In practice, in some instances the screw is screwed down such that the receiver touches the bone; is that right?

> A. I'm sure some surgeons do that. And it can touch the bone and still move a little because the bone is elastic. And the tissue right on top of the bone isn't necessarily bone. It's periosteum. It's deformable.

Medtronic counters with an April 22, 2004, declaration from Kevin Foley, M.D., a board certified neurosurgeon, who has performed over 500 operations using Medtronic's allegedly infringing products. Dr. Foley states, in pertinent part, that:

> [i]n all of the surgeries I perform using Medtronic Products, I try to minimize or avoid contact of any part of the receiver member to the patient's spinal anatomy to ease the eventual implantation of the rod. I do not count on any type of direct connection between the receiver member and the patient's spine to impart any stability to the spine or to the implant construct....
>
> When implanting the Medtronic Products in a patient's spine, any contact between the receiver member and any portion of the patient's anatomy is incidental to the surgery and not intended to impart any stability to the spine. In fact, when I instruct other spine surgeons in how to implant the Medtronic Products, I tell them that if they tighten down on the bone screw enough to bring the receiver member into engagement with the spine, they should back off the bone screw by one-quarter to one-half turn so as to better enable alignment of the receiver members with the rod.

Thus, Sherman—who is not testifying that he witnessed contact—speculates that some surgeons may bring the receiver member into contact with bone. Dr. Foley confirms that from time to time, "incidental to the surgery," the receiver member comes into contact with bone. However, Dr. Foley also suggests that he "tr[ies] to minimize or avoid contact" and instructs others to "back off the bone screw by

one quarter to one-half turn" "if they tighten down on the bone screw enough to bring the receiver member into engagement with the spine."

On the one hand, drawing inferences in favor of Medtronic, a reasonable juror could conclude that the apparatus is not made because, more likely than not, there is no contact between the receiver member and the bone. On the other hand, drawing inferences in favor of Cross Medical, a reasonable juror could conclude that the apparatus is made by surgeons. Sherman's statements suggest that the device is capable of posterior stabilization when the receiver member contacts bone, and the statements of both Sherman and Dr. Foley suggest that there may be some contact between the receiver member and the spine. We leave it to the fact finder to decide whether surgeons directly infringe.

As to inducement, there is a genuine issue of material fact both as to whether Medtronic "knowingly induced infringement" and as to whether Medtronic "possessed specific intent to encourage [the surgeons'] infringement." On the one hand, in the record are Medtronic's "Field Bulletins" instructing surgeons that the proper technique for installation of the Medtronic device is with the receiver member not in contact with the bone. Medtronic asserts that these materials, together with Dr. Foley's statement, show that it had no knowledge that the surgeons made the claimed apparatus and that it had no specific intent to encourage infringement. On the other hand, Cross Medical points to Sherman's statements—that he would instruct surgeons to screw the receiver member down "as far as they feel comfortable doing and still have some rotation" and that "[the receiver member] can touch the bone and still move a little because the bone is elastic"—as evidence that Medtronic anticipated that surgeons would contact bone and intended that the device function when in contact with bone. Drawing inferences in favor of Medtronic, a reasonable juror could find that Medtronic did not know that surgeons make

the claimed apparatus and, moreover, did not specifically intend for surgeons to contact bone with the anchor seat. Drawing inferences in favor of Cross Medical, a reasonable juror could find that Medtronic designed its device to function when the anchor seat contacted bone, anticipated that surgeons would contact the anchor seat to bone, and thus intended for the surgeon to make or use the apparatus as claimed.

As to contributory infringement, there is a genuine issue of material fact as to whether there are substantial non-infringing uses of Medtronic's devices, specifically, uses of the devices with no receiver member-to-bone contact. Drawing inferences in favor of Medtronic, a reasonable juror could conclude, based on Dr. Foley's statements, that a substantial number of surgeries occur in which the claimed apparatus is not made or used, as surgeons are able to avoid contact between the seat and bone. Drawing inferences in favor of Cross Medical, a reasonable juror might also conclude that in almost every surgery, the claimed apparatus is made or used, as some contact between the receiver member and the bone is incidental.

Therefore, the district court erred in ruling both that there were no genuine issues of material fact as to infringement and that Medtronic infringed as a matter of law.

2. "*securing means*"

The district court ruled that Medtronic's "set screw" is equivalent to the external nut as a matter of law because it performs compression in "substantially the same way" to achieve "substantially the same result" as the "external nut." *Infringement Opinion* at 6. The district court cited testimony that the set screw has opposite points of contact on the rod 180 degrees apart, noted that the screw is intended to be coaxial with the anchor means, and explained that "[a]lthough Plaintiff does not provide tests showing the magnitude of the force on either side, everything before the Court supports the conclusion the forces are substantially

equal." *Id.* at 7. The district court added that "[d]efendants submit[ed] no evidence to show the forces are not equal." *Id.* The district court reasoned: "[v]iewing the devices themselves and the testimony, it appears Defendants' inner screw meets the limitation applying substantially equal compressive forces on either side of the channel." *Id.*

Medtronic argues that a set screw is not equivalent to an external nut as a matter of law, citing *Chiuminatta Concrete Concepts Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303 (Fed.Cir.1998). Medtronic notes that the '555 patent's express reference to the use of a set screw to attach a cross-link to the rod, but lack of a reference to a set screw to lock the rod to the anchor seat, is compelling evidence of non-equivalents. In addition, Medtronic asserts that set screws and external nuts are not interchangeable because set screws apply a "splaying" force to the side walls of the anchor seat while external nuts do not; an external nut applies compressive forces to the rod in a way that bows or bends the rod upwardly in the anchor seat channel while the set screw minimizes this type of load on the rod; and bowing creates a problem in Medtronic's devices. Medtronic adds that Dr. Puno, an inventor of the '555 patent, testified that a set screw and an external nut were not interchangeable. Medtronic portrays as unsupported the views of Dr. Villarraga, Cross Medical's expert, who opined that the set screw and external nut are interchangeable. Medtronic argues that Cross Medical has offered no evidence that the set screw applies "substantially equal compressive forces" to the rod; and asserts that Michael Sherman offered convincing testimony that they do not. Medtronic asserts that at the least, there is a genuine issue of material fact as to whether the set screw is an equivalent.

Cross Medical argues that a set screw and external nut perform the function of compression in substantially the same way—applying a downward force on a rod achieved by engaging threads of the receiver—to achieve the identical

result—securing the rod in the channel; and that *Chiuminatta* is distinguishable. Cross Medical cites evidence that the set screw applies force to opposite sides of the channel. Cross Medical asserts that, because the compression being applied from the set screw to the rod would be through absolutely equal forces applied on either side of the channel absent machining imperfections and patient physiology, if one were to account for these factors, the forces would be substantially equal. Cross Medical argues that "splaying" and "bowing" do not affect equivalents and that Dr. Villarraga's opinion on interchangeability is properly based on her knowledge of mechanical engineering and her examination of the devices. Cross Medical asserts that Dr. Puno's testimony on interchangeability is irrelevant. Cross Medical argues that Medtronic admitted in U.S. Patent No. 6,660,004 ("the '004 patent") that the set screw and external nut were interchangeable. Cross Medical additionally asserts that because Medtronic argued that a set screw and external nut are equivalent to invalidate claims of another patent, Medtronic is estopped from asserting that they are not equivalent.

"'Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification.'" *Frank's Casing*, 389 F.3d at 1378 (quoting *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed.Cir.1999)). "Because structural equivalents under § 112, ¶ 6 are included within literal infringement of means-plus-function claims, 'the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for the structure.'" *Id.* (quoting *Pennwalt Corp. v. Durand–Wayland, Inc.*, 833 F.2d 931, 934 (Fed.Cir.1987) (en banc) (emphasis omitted)). "This inquiry for equivalent structure under § 112, ¶ 6 examines whether 'the assertedly equivalent

structure performs the claimed function in substantially the same way to achieve substantially the same result ....'" *Id.* (quoting *Odetics*, 185 F.3d at 1267).

At the outset, we conclude that Medtronic is not estopped from challenging interchangeability. In this case, Medtronic argued that a set screw and external nut are functionally equivalent for purposes of invalidating claim 10 of the '237 patent. However, that argument has no bearing on Medtronic's challenge to the interchangeability of a set screw and an external nut with respect to claim 5 of the '555 patent because the functions of the "securing means" in claim 5 of the '555 patent and claim 10 of the '237 patent are different. Claim 10 does not require the application of substantially equal compressive forces to the rod on either side of the channel. *See* '237 patent, col. 4, ll. 42–58, ll. 61–63; col. 5, ll. 14–22. Because the positions are not entirely inconsistent, judicial estoppel does not apply. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1345 (Fed.Cir.2001) ("[A] party will be judicially estopped from asserting a position on appeal that is directly opposed to a position that the party successfully urged at trial." (internal citations omitted)).

As to the merits, the claimed function has two parts: (1) causing the rod to bear against the channel by applying a compressive force in the direction of the vertical axis; and (2) ensuring that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides—either inside or outside—of the rod-receiving channel. There is no dispute that the set screw applies a compressive force in the direction of the vertical axis. However, there is a genuine issue of material fact as to whether the set screw applies substantially equal forces on opposite sides of the channel, and thus whether there is identity of function.

On the one hand, Cross Medical cites testimony stating that the v-ring on the bottom of the internal set screws creates two points of contact when the set screws are

compressed against the rod; that the two points of contact between the set screw and the rod are 180 degrees apart, separated by the drive in the set screw; and that the set screw is intended to be co-axial with the receiver (but because of manufacturing tolerances is not co-axial). (Sherman Dep. of Jan. 29, 2004, at 137–41; Sherman Dep. of Jan. 30, 2004, at 283–84.) On the other hand, Medtronic cites testimony stating that Sherman did not know if the load on the points of contact on either side of the v-ring were equal; that when the implant is functioning in a patient, the screw takes on additional load from the rod; and that anytime the screw is loaded, load will increase on one side of the plug such that forces on the two sides would be unequal. (*Id.* at 365–66.) Sherman further testified that he did not know if forces would be equal before the screw and anchor seat were implanted, because manufacturing tolerances might impact the forces. (*Id.* at 366–67.) Drawing inferences in favor of Medtronic, a reasonable juror could find that the forces are not substantially equal on each side of the channel because of manufacturing tolerances and the additional load placed on the screw by the rod when implanted. Crediting Cross Medical's evidence, a reasonable juror could draw an inference based on Sherman's testimony that the forces applied to the rod on either side of the channel are substantially equal.

Moreover, there is a genuine issue of material fact as to whether the set screw accomplishes the claimed function in substantially the same way as the external nut. Medtronic has cited the testimony of Dr. Puno stating that he considered using a set screw in 1990 to hold the rod in place but decided against the set screw because of splaying concerns. (Puno Dep. of April 9, 2004, at 32, l. 10–36, l. 24.) Dr. Puno stated that having the side walls of the anchor seat spread apart when the screw was tightened down would be "a bad thing" and "could end up loosening the connection on the rod." (*Id.* at 35, ll. 7–14.) Although Dr. Puno testified that he thought

a set screw and external nut were interchangeable, he qualified his statement when confronted with prior deposition testimony to the opposite effect. (*Id.* at 37, l. 3–41, l. 23.) Dr. Villarraga stated that the structures were interchangeable because they both could compress a rod into a channel, and because other polyaxial devices utilized set screws. (Villarraga Decl. of April 12, 2004, at 2.) However, Dr. Villarraga neither explained with any specificity why one of ordinary skill in the art at the time the '555 patent issued would believe the structures to be interchangeable, nor did she refer to any testing. (*See id.*) Drawing inferences in favor of Medtronic, a reasonable juror could find that the set screw does not compress the rod in substantially the same way based on Dr. Puno's testimony about the potential for splaying and his conscious decision to avoid the setscrew design. Drawing inferences in favor of Cross Medical, a reasonable juror could find that the set screw compresses the rod in substantially the same way because both employ threads as a compression mechanism, and some statements of Drs. Puno and Villarraga support a finding of interchangeability.

We thus disagree with Medtronic that the equivalents question should be removed from the trier of fact under *Chiuminatta*. In that case, we held that no reasonable juror could conclude that the differences between "soft round wheels" and a "skid plate" were insubstantial. *Chiuminatta*, 145 F.3d at 1310. One of the many reasons that we found no equivalents as a matter of law was that the patent at issue discussed the use of wheels for another function, but never disclosed that wheels could perform the same function as the skid plate. *Id.* In this case, although Medtronic may argue that the fact finder should draw an inference of no interchangeability based on the inventors' explicit reference to set screws to form a cross-link, *see* '555 patent, col. 6, ll. 25–44, and their failure to explicitly recognize set screws as a means for securing the anchor to the bone, we must draw

inferences in favor of Cross Medical in evaluating Medtronic's cross-motion for summary judgment. As discussed *supra*, we believe that the issue of interchangeability should be left for the trier of fact.

We also reject the other arguments that both sides make in attempting to prevail on equivalents as a matter of law. First, we reject Cross Medical's argument that the '004 patent serves as an admission on interchangeability. Even though the '004 patent, which is assigned to an entity related to Medtronic, suggests that an "internally-threaded nut" is interchangeable with "a set screw or internal plug," '004 patent, col. 8, ll. 10–32, that patent issued in 2003 and is irrelevant to known interchangeability in 1995, when the '555 patent issued. *See Al-Site*, 174 F.3d at 1320 ("[A] structural equivalent under § 112 must have been available at the time of the issuance of the claim."). Second, we reject Medtronic's contentions that the lack of "bowing" with the set screw and the evidence that the external nut does not function to cause "bowing" in Medtronic's device are relevant to interchangeability. Even if the external nut causes "bowing" in Medtronic's device, it is immaterial to the equivalents analysis because "prevention of bowing" is not a limitation of claim 5. *See Micro Chem.*, 194 F.3d at 1258 (cautioning against adopting a function different from that explicitly recited in the claim). Furthermore, although Medtronic argues that the external nut may not work well in Medtronic's products, any impact this might have on the interchangeability analysis is undercut by a lack of evidentiary support.

In summary, we conclude that there is a genuine issue of material fact with respect to whether a set screw is equivalent to an external nut. Thus, the district court erred in deciding equivalents as a matter of law.

3. "*bear against said channel*"

Relying on its holding that the channel of the anchor seat could comprise more than one component, the district

court ruled that, even if the crown is free-floating and not physically joined to the anchor seat because there is no lock between the crown and the screw, Medtronic's devices met the "bear against said channel" limitation as a matter of law. *Infringement Opinion* at 7–8. The district court considered evidence that the crown member is physically joined to the anchor seat because it cannot be removed without breaking the screw. *Id.* The district court analogized the crown in Medtronic's devices to a "pressure disk"—which was physically between the rod and the anchor seat—that the district court previously had held met the "bear against the channel" limitation in *Cross Medical Products, Inc. v. DePuy Acromed, Inc.*, No. SA CV 00-876-GLT (ANx), (C.D.Cal. Feb. 11, 2002). *Infringement Opinion* at 7.

Medtronic argues that even if the anchor seat can be comprised of multiple components, as a matter of fact, the crown member in its accused devices is not part of the channel formed by the anchor seat and, thus, the rod does not bear against the channel as recited in the claim. Medtronic asserts that the crown is free floating and not physically or otherwise joined to the receiver; that the crown is either screwed or slid into the receiver; and that the crown is retained either by a snap ring or by interrupting the threads on the receiver after the crown is screwed into the receiver. Medtronic adds that the presence of the crown between the rod and the bone screw causes the receiver member to become rigidly locked to the screw, which serves a different function than a channel absent a crown member.

Cross Medical counters that there is nothing to preclude a finding that the crown is part of the anchor seat. Cross Medical argues that the crown member is part of the channel formed by the anchor seat because the crown is assembled into the device before it is sold, and cannot be removed without damaging the device. Cross Medical asserts that the crown is physically joined to the receiver, and adds that any

difference in function is irrelevant because claim 5 has no functional limitation.

There is a genuine issue of material fact as to whether the "bear against [the] channel" limitation is met by the accused products. Sherman testified that in one product, "the crown member is threaded and screws down into the receiver member until it passes the threads of the receiver member and then floats freely until locked down by the rod." (Sherman Decl. of April 23, 2004, at 3.) Sherman stated that in other products, "the crown member is maintained in the receiver member by a snap ring that is designed to allow the crown 'member' to float or move freely within a limited range" before being locked down by the rod. (*Id.*) Sherman added that the rod touches only the crown member in each of Medtronic's products. (*Id.* at 3–4.) Viewing this evidence in the light most favorable to Medtronic, a reasonable juror could conclude that the rod bears only against the crown member, which is separate from the channel in the anchor seat, and thus the rod does not "bear against" the channel of the anchor seat.

However, a reasonable juror could also find that the crown member is a part of the channel, and thus that the rod bears against the channel. Cross Medical cites to evidence that the screw, crown, snap ring, and receiver are assembled as one unit before the implant arrives to the surgeon. (Sherman Dep. of Jan. 29, 2004, at 123.) Cross Medical also cites evidence that the snap ring, which holds the crown member loosely in place, is damaged if the implant is disassembled. (*Id.* at 247.) And we agree with Cross Medical that the function served by the crown member is irrelevant to finding that this structural limitation is met. *See Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed.Cir.1984) ("[M]odifications by mere *addition* of elements of function ... cannot negate infringement ....").

Because there is a genuine issue of material fact as to whether the "bear against [the] channel" limitation is met,

the district court erred in ruling that the accused devices met this limitation as a matter of law.

E. Invalidity

The district court granted Cross Medical's cross-motion for partial summary judgment on all invalidity defenses raised by Medtronic with respect to claim 5 of the '555 patent, including indefiniteness, anticipation, and obviousness. Medtronic appeals each of these rulings.

1. Indefiniteness

As noted in Part II.C.3 *supra*, Medtronic argued that the district court erroneously interpreted the function of the "securing means" to require that equal forces be applied along the longitudinal axis of the channel on "either side" of the vertical axis. Medtronic asserted that the district court's interpretation would leave "said longitudinal axis" without a sufficient antecedent basis and render claim 5 indefinite. We construed the function of the "securing means" limitation as "to cause the rod to bear against the rod-receiving channel by applying a compressive force in the direction of the vertical axis, while ensuring that substantially equal forces are applied along the longitudinal axis of the rod on opposite sides—either inside or outside—of the rod-receiving channel." We agreed with Medtronic that the antecedent basis for "said longitudinal axis" was by implication the longitudinal axis of the rod. *See Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116 (Fed.Cir.1987) (noting that an antecedent basis can be present by implication). Because the "said longitudinal axis" limitation is not lacking in antecedent basis, we conclude that the district court did not err in granting Cross Medical's motion for summary judgment that claim 5 is not indefinite.

2. Anticipation

The district court held that claim 5 was not anticipated as a matter of law because claim 5 covers only polyaxial screws and the two prior art references asserted to be anticipating—U.S. Patent No. 4,763,644 to Webb ("the '644

patent") and the "Bryd-Transpedicular Spinal Fixator"—disclose only monoaxial screws. *Invalidity Opinion* at 5. Medtronic's arguments on anticipation turn entirely upon whether claim 5 covers monoaxial screws. Because we determined in Part II.C.1 *supra* that claim 5 does not cover monoaxial screws, we conclude that the district court did not err in granting Cross Medical's motion for partial summary judgment that claim 5 is not anticipated.

3. Obviousness

In the district court, Medtronic contended that claim 5 was obvious in view of the '602 patent, the '644 patent, and the Byrd device. *Invalidity Opinion* at 6. The parties agreed that the '602 and '644 patents were prior art, but the district court held that because Dr. Puno, an inventor on the '555 patent, also invented the closure mechanism of the Bryd device, the Bryd device was not prior art. *Id.* at 6. Focusing on the '602 and '644 patents, the district court explained that the '602 patent and the '555 patent are both polyaxial spinal implant devices. *Id.* The district court noted that "[t]he only major difference between the '602 patent and the '555 is the '602 device is tightened from the bottom and the '555 is a top-loading nut," but that "[t]he '644 patent covers a top-loading monoaxial spinal implant device." *Id.* at 7. However, the district court held that there was no motivation to combine the '602 and '644 references, relying on its prior ruling in *Cross Medical Products, Inc. v. DePuy AcroMed, Inc.*, No. SA CV 00-876-GLT(ANx) (C.D.Cal. Jan. 9, 2003).

In *AcroMed*, the defendant had argued that "the top-loading nut would have been obvious in light of the problem to be solved, i.e., surgeons having difficulty tightening the bottom-loading nuts during implantation." *Invalidity Opinion* at 7. The district court "found AcroMed failed to show motivation to combine because 'the problem was not discovered by looking at the prior art or the patent itself.... It was only discovered when doctors tried to use the product.'" *Id.* The court cited *In re Sponnoble*, 56 C.C.P.A. 823, 405

F.2d 578, 585 (1969), for the proposition that "'a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified.'" *Invalidity Opinion* at 7.

The district court found that Medtronic offered no evidence that the problem was disclosed in the prior art. *Id.* The district court noted that "Defendants cite only the '555 patent to describe the problem the '555 patent sought to fix." *Id.* The district court explained that "[a]lthough Defendants argue the clinical investigators identified the problem with the bottom-loading nut, the investigators' letters are not prior art." *Id.* The district court acknowledged that "motivation to combine need not be explicit in the prior art; 'it can be implicit in the knowledge of one of skill in the art,'" *id.* (quoting *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1337 (Fed.Cir.2004)), but reasoned that "[t]his rule does not change the result in this case because it does not relate to identification of the problem," *id.* at 7. The district court then denied Medtronic's motion for summary judgment on obviousness and granted Cross Medical's cross motion. *Id.* at 7–8.

Medtronic argues that it presented sufficient evidence that the bottom-tighteningnut problem was known to those of ordinary skill in the art and that this provides a motivation to combine the '644 and '602 references. Medtronic cites communications from clinical investigators as evidence of recognition of the problem by those of ordinary skill in the art, and argues that the district court's analysis and adoption of the reasoning in *Sponnoble* were in error. In addition, Medtronic cites: (a) the '644 patent as evidence that bottom-tightening devices then available were problematic to assemble in situ; (b) U.S. Patent No. 5,261,913 ("the '913 patent") as evidence that it was within the knowledge of one of ordinary skill to use a top-tightening nut; and (c) the '555 patent as evidence that prior art polyaxial screws designed

with bottom-tightening nuts were awkward.[3] Medtronic argues that even if the '913 patent does not qualify as prior art, it evidences knowledge of one of ordinary skill in the art. Medtronic asserts that, at the least, this evidence is enough to create a genuine issue of material fact on motivation to combine.

Cross Medical counters that Dr. Puno was one of the clinical investigators who recognized the problem with the '602 device, that Dr. Puno discovered the problem as part of his inventive process, and thus that the clinical investigators' recognition of the problem is not evidence of a motivation to combine. Cross Medical argues that the '644 patent does not itself provide reason to apply its teachings to modify the '602 device because it discusses prior art assembly problems related to use of a locking nut and threaded rod to hold the screw. Cross Medical argues that the '602 device did not use a threaded rod with a locking nut, and thus the inventors did not confront the same problem as confronted by the inventors of the '644 device. Cross Medical asserts that the

---

[3] In a footnote in its opening brief, Medtronic asserts that the district court erroneously resolved a fact question as to whether Dr. Puno was an inventor of the Bryd device but never requests relief or provides record cites for its assertions. Medtronic makes no other reference to the Bryd device with respect to obviousness in its opening brief. In its response brief, Medtronic asserts that even if Dr. Puno is a joint inventor of the Bryd device, there is a different set of joint inventors on the Bryd device—Drs. Puno and Bryd--than on the '555 patent—Dr. Puno and Mellinger. Medtronic argues that the two sets of inventors are separate legal entities under *In re Kaplan*, 789 F.2d 1574, 1575 (Fed.Cir.1986), and that the Bryd device may be prior art under §§ 102(f) and 103. Medtronic adds that even if the Bryd device is confidential, it evidences knowledge of those of ordinary skill.

Medtronic has not properly raised the inventorship issue in its opening brief to warrant relief from this court. *See Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1375 n. 4 (Fed.Cir.2005) (holding that this court will not address arguments that are not properly raised in the opening brief). Nor will this court consider Medtronic's new arguments raised for the first time in its reply brief. *Id.*

'913 patent cannot evidence knowledge of ordinary skill in the art at the time of the invention because the application that matured into the '913 patent was filed two months after the invention date of the '555 patent, and that application was not published for 18 months. Cross Medical cites differences between the '602 and '555 patents in addition to the bottom-tightening nut, and asserts that Medtronic submitted no evidence explaining how the particular structural elements of the '602 device could be modified to achieve the structure disclosed in claim 5 as a whole. Cross Medical argues that Medtronic failed to discuss "trade-offs" to the use of the top-tightening device, and neglected to discuss secondary considerations.

"A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1369 (Fed.Cir.2000); *see* 35 U.S.C. § 103. An invention may be a combination of old elements disclosed in multiple prior art references. *Kotzab*, 217 F.3d at 1369. In determining whether a combination of old elements is non-obvious, the court must assess whether, in fact, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference. *See In re Fulton*, 391 F.3d 1195, 1200-02 (Fed.Cir.2004). Motivation to combine references "may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *Kotzab*, 217 F.3d at 1370. "The test for an implicit teaching is what the combined references, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *Id.*

The sole issue before us is whether the district court erred in ruling that there is no genuine issue of material fact as to whether the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time of the invention based on the absence of any evidence of a motivation to combine the '602 and '644 references. We conclude that a genuine issue of material fact exists with respect to motivation to combine. Cross Medical designated the screw disclosed in the '602 patent as the "PWB I" and performed a pilot study testing its use in humans. A paper, entitled "The Puno-Winter-Bird (PWB) Spinal System for Transpedicular Fixation of the Lumbar Spine," recounted that surgeons participating in the pilot study found the implant design "tedious," and that it was "technically difficult to position the wrench when the nut was tightened, since it required that the nut be advanced from under the rod." The paper explained that "[a]lthough [the PWB I] provided satisfactory fixation of the rod, the design was not 'user friendly.'" The paper noted that "[a] design improvement was in order and led to the development of the PWB II." Other evidence in the record confirms that surgeons in the pilot study recognized the problem and requested changes. The surgeons who participated in the pilot included investigators other than inventors of the '555 patent.

From this evidence, a reasonable juror could conclude that at the time of the invention, one of ordinary skill in the art could have been motivated to modify the PWB I in light of the problem to be solved. Giving credit to Medtronic's evidence, the clinical investigators recognized the bottom-tightening problem with the '602 device and proposed changes. The problem was within the general knowledge of those of ordinary skill in the art, and thus provided sufficient motivation to navigate the prior art in the spinal implant field in search of a teaching on how one might modify the '602 device away from a bottom-tightening assembly.

The district court erred in discounting the clinical investigators' recognition of the problem. "It has long been the law that the motivation to combine need not be found in prior art references, but equally can be found 'in the knowledge generally available to one of ordinary skill in the art.'" *Nat'l Steel*, 357 F.3d at 1337 (quoting *In re Jones*, 958 F.2d 347, 351 (Fed.Cir.1992)). Evidence of a motivation to combine references need not be in the form of prior art. *See id.* at 1338–39. Evidence that a person of ordinary skill in the art recognized the same problem to be solved as the inventor and suggested a solution is, at the least, probative of a person of ordinary skill in the art's willingness to search the prior art in the same field for a suggestion on how to solve that problem. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed.Cir.1996) (Motivation to combine "may also come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." (citing *Application of Rinehart*, 531 F.2d 1048, 1054 (C.C.P.A.1976))); *In re Huang*, 100 F.3d 135, 139 n. 5 (Fed.Cir.1996) (stating that problem well-known to a person of ordinary skill in the art would have directed that person of ordinary skill to the reference teaching the missing elements); *see also, e.g., In re Gartside*, 203 F.3d 1305, 1320–21 (Fed.Cir.2000) (recognizing that motivation to combine can come from the nature of the problem to be solved); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed.Cir.1998) (same). To the extent that the district court determined that the only investigators who recognized the problem of the bottom-tightening assembly were inventors on the '555 patent, that conclusion has no basis in the record.

Furthermore, the district court's reliance on *Spommoble* is misplaced. In that case, those of ordinary skill in the art of packaging pharmaceutical products recognized a moisture-transfer problem with "structure[s] for temporarily isolating a compartment containing a solid pharmaceutical product

from a compartment containing an aqueous solution." *Sponnoble*, 405 F.2d at 585. The industry believed that moisture was transmitted *around* the plug separating the two compartments. *Id.* at 586. Sponnoble discovered that moisture traveled *through* the plug and remedied that problem with a solution available in the prior art. *Id.* Our predecessor court held that the invention was non-obvious because one of ordinary skill in the art would not have chosen the solution without recognizing the true cause of the problem, and "the cause of the problem [was] not suggested by the prior art." *Id.* In this case, however, the problem was known to the clinical investigators at the time of the invention, and thus, unlike *Sponnoble*, the problem was within the general knowledge of one of ordinary skill in the art. *See Nat'l Steel*, 357 F.3d at 1338 ("Something that has already been rendered obvious to a newcomer in the field is probative of what would be obvious to someone who has been around for a longer period of time."). If the problem is within the knowledge of one of ordinary skill in the art, then it is irrelevant that the prior art does not disclose the problem. *See id.* at 1337–39.

Moreover, we conclude--after drawing inferences in favor of Medtronic—that the '644 patent itself may have provided sufficient motivation for one of ordinary skill to have considered its teachings and altered the '602 device. The '644 invention was an improvement over prior art spinal implant devices which used a threaded rod with locking nuts. In characterizing the prior art, the patent states that "[t]he need to thread the nut along the rod results in the device being rather slow to assemble and can result in damage to soft tissue if carried out in situ." '644 patent, col. 2, ll. 10–12. The solution was, in part, a top-tightening nut. *See id.*, col. 3, ll. 16–23; *id.*, Figure 2. Thus, the '644 patent discusses a problem posed by the assembly of certain spinal stabilization devices in situ and a solution. Confronted with the implantation problem of the '602 device, one of ordinary

skill might have found the problem solved by the '644 patent sufficiently analogous to have been motivated to apply its teachings. In turn, we reject Cross Medical's contention that the '644 device cannot provide the requisite motivation because the problem it addressed may have differed slightly from the problem encountered by surgeons using the '602 device. One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings. *See In re Oetiker*, 977 F.2d 1443, 1448 (Fed.Cir.1992) (Nies, C.J., concurring) ("Such suggestion or motivation to combine prior art teachings can derive solely from the existence of a teaching, which one of ordinary skill in the art would be presumed to know, and the use of that teaching to solve *the same or similar problem* which it addresses." (citing *In re Wood*, 599 F.2d 1032, 1037 (1979)) (emphasis added)); *cf. In re Dillon*, 919 F.2d 688, 694 (Fed.Cir.1990) (en banc) ("'[A reference is not from a non-analogous art if] the reference is reasonably pertinent to the particular problem with which the inventor was involved.'" (quoting *In re Deminski*, 796 F.2d 436, 442 (Fed.Cir.1986) (quoting in turn from *Wood*, 599 F.2d at 1036))).

As to the other evidence cited by Medtronic, the '555 patent suggests that the inventor recognized the problem of bottom-tightening. However, the patent does not provide evidence that the problem was within the knowledge of those of ordinary skill in the art at the time of the invention; or that the problem was disclosed in the prior art. The '913 patent is also of limited relevance because it issued after the invention date. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576–77 (Fed.Cir.1996).

Thus, we conclude that, because there are genuine issues of material fact on the underlying facts related to obviousness, the grant of summary judgment was in error.

III. CONCLUSION

We conclude that we have jurisdiction over this appeal. We affirm the district court's construction of the "anchoring means," "securing means," and "bear against said channel" limitations, but modify the district court's construction of the "operatively joined" and the "anchor seat means" limitations. Because we find genuine issues of material fact regarding infringement, we reverse the grant of Cross Medical's motion for partial summary judgment of infringement and find no abuse of discretion in the denial of Medtronic's cross-motion for partial summary judgment of non-infringement. We also reverse the grant of Cross Medical's motion for partial summary judgment that claim 5 is not obvious but affirm the grant of that motion as to indefiniteness and anticipation. We further conclude that the district court did not abuse its discretion in denying Medtronic's cross-motion for summary judgment as to these invalidity issues. As a result, we vacate the permanent injunction. We remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED.

COSTS

Costs to Medtronic.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1415

CROSS MEDICAL PRODUCTS, INC.,
Plaintiff-Appellee,

v.

MEDTRONIC SOFAMOR DANEK, INC. and
MEDTRONIC SOFAMOR DANEK USA, INC.,
Defendants-Appellants.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellee, and a response thereto having been invited by the court and filed by the Appellant, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on May 22, 2007.

Circuit Judge Dyk did not participate in the vote.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 05/15/2007

cc: Dirk D. Thomas
Bruce D. Kuyper

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT
MAY 15, 2007
JAN HORBALY
CLERK

CROSS MEDICAL V MEDTRONIC SOFAMOR, 2005-1415 (DCT - 8:03-CV-00110)

69

No. 07-186

FILED
OCT 9 - 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

CROSS MEDICAL PRODUCTS, INC.,

Petitioner,

v.

MEDTRONIC SOFAMOR DANEK, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

DIRK D. THOMAS
Counsel of Record
ROBERT A. AUCHTER
JEFFREY I. FREY
DEWEY & LEBOEUF LLP
975 F Street, N.W.
Washington, D.C. 20004-1405
(202) 862-1000

Counsel for Respondents

October 9, 2007

211553

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the Court of Appeals for the Federal Circuit found correctly, under the facts of this case, that the rationale underlying plaintiff's narrowing amendment to its patent claim bore more than a tangential relation to the accused equivalent, such that plaintiff could not rebut the presumption of prosecution history estoppel.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

Respondents Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc., are defendants and counter-claimants in the district court proceedings and were appellants in the court of appeals proceedings. Counter-claimant SDGI Holdings, Inc. is a party to the district court proceedings only.

Respondents and counter-claimants are wholly owned subsidiaries of Medtronic, Inc., a publicly traded corporation. No publicly held company owns 10% or more of Medtronic, Inc.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	1
JURISDICTION	2
STATEMENT OF THE CASE	2
I. HISTORY OF U.S. PATENT NO. 5,574,555	4
REASONS FOR DENYING THE PETITION	8
A. The Interlocutory Posture of This Case Makes Review Inappropriate.	9
B. The Question Presented By Petitioner Does Not Satisfy The Requirements of This Court's Rule 14.1(a).	10

Contents

Page

C. Determination Of The Scope Of Estoppel Under The Doctrine Of Equivalents Is An Intensely Factbound Application Of The Law To The Particular Facts Of Each Case And The Decision Below Presents No Clear-Cut Question Of Law For Consideration By This Court. 12

D. The Federal Circuit Faithfully Applied This Court's and the Federal Circuit's Law To These Facts When Deciding That Plaintiff Failed to Rebut the Presumption of Prosecution History Estoppel. 14

E. The Federal Circuit's Decision In This Case Is Consistent With Other Federal Circuit Decisions. 16

F. The Federal Circuit Has Neither "Eviscerated" The Tangential Relation Principle Nor Created A New Test. 20

CONCLUSION 21

TABLE OF CITED AUTHORITIES

Page

Cases

Amgen Inc. v. Hoechst Marion Roussel, Inc.,
457 F.3d 1293 (Fed. Cir. 2006) 16

Bhd. of Locomotive Firemen & Enginemen v. Bangor & Aroostook R.R. Co.,
389 U.S. 327 (1967) 10

Biagro W. Sales, Inc. v. Grow More, Inc.,
423 F.3d 1296 (Fed. Cir. 2005) 16

Bus. Objects, S.A. v. MicroStrategy, Inc.,
393 F.3d 1366 (Fed. Cir. 2005) 16

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
535 U.S. 722 (2002) ("*Festo VIII*") ..... *passim*

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,
344 F.3d 1359 (Fed. Cir. 2003) ("*Festo IX*") .. 14, 16

Glaxo Wellcome, Inc. v. Impax Labs., Inc.,
356 F.3d 1348 (Fed. Cir. 2004) 16

Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.,
240 U.S. 251 (1916) 10

Insituform Techs., Inc. v. CAT Contr., Inc.,
385 F.3d 1360 (Fed. Cir. 2004) 16, 18, 19, 20

Cited Authorities

Page

Litton Sys., Inc. v. Honeywell, Inc.,
140 F.3d 1449 (Fed Cir. 1998) 12

Mycogen Plant Sci., Inc. v. Monsanto, Co.,
91 Fed. Appx. 666 (Fed. Cir. 2004)
(nonprecedential) 16

Okor v. Atari Games Corp.,
76 Fed. Appx. 327 (Fed. Cir. 2003)
(nonprecedential) 16

Pioneer Magnetics, Inc. v. Micro Linear Corp.,
330 F.3d 1352 (Fed. Cir. 2003) 16

Primos, Inc. v. Hunter's Specialties, Inc.,
451 F.3d 841 (Fed. Cir. 2006) 16, 20

Research Plastics, Inc. v. Fed. Packaging Corp.,
421 F.3d 1290 (Fed. Cir. 2005) 16, 17

Rhodia Chimie v. PPG Indus.,
402 F.3d 1371 (Fed. Cir. 2005) 16

Talbert Fuel Sys. Patents Co. v. Unocal Corp.,
347 F.3d 1355 (Fed. Cir. 2003) 16

Taylor v. Freeland & Kronz,
503 U.S. 638 (1992) 12

Terlep v. Brinkmann Corp.,
418 F.3d 1379 (Fed. Cir. 2005) 16

Cited Authorities

Page

United States v. Johnston,
268 U.S. 220 (1925) 13

Va. Military Inst. v. United States,
508 U.S. 946 (1993) 10

Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,
520 U.S. 17 (1997) ..... *passim*

Yee v. City of Escondido,
503 U.S. 519 (1992) 11

Statutes

28 U.S.C. § 1254(1) (2007) 2

35 U.S.C. § 102 (2007) 1, 3, 5, 7, 14

35 U.S.C. § 112 (2007) ..... *passim*

35 U.S.C. § 271 (2007) 1

35 U.S.C. § 282 (2007) 10

Page

Other Authorities

Cross Med. Prods. Inc. v. Medtronic Sofamor Danek, Inc., No. 05-1415 (Fed. Cir. Dec. 12, 2005), Non-Confidential Joint Appendix 4

Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 480 F.3d 1335 (Fed. Cir. 2007) ..... *passim*

Rules

Sup. Ct. R. 14.1 ..... 8, 10, 11

Constitutional Provisions

U.S. Const. Art. I, § 8, cl. 8 1

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

In addition to Article 1, Section 8, Clause 8 of the United States Constitution, and 35 U.S.C. § 271(a), cited by Petitioner, this case also involves 35 U.S.C. § 112 and 35 U.S.C. § 102(b).

The relevant paragraphs of § 112 state:

¶ 1. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

¶ 2. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicants regards as his invention.

The relevant section of 35 U.S.C. § 102 states:

A person shall be entitled to a patent unless–

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

JURISDICTION

While this Court has jurisdiction under 28 U.S.C. § 1254(1), it should be noted that this is an interlocutory appeal. The Court of Appeals for the Federal Circuit, after reversing and vacating the District Court's summary judgment rulings on invalidity and infringement, remanded the case to the District Court for further proceedings consistent with the two opinions that the Federal Circuit has issued in this case. Pet. App. 17a.

STATEMENT OF THE CASE

This case is currently pending in the District Court for the Central District of California. Pet. App. 112a. The District Court was instructed by the Federal Circuit to conduct further proceedings on Petitioner's claims of infringement and respondents' affirmative defenses and counterclaims of invalidity consistent with the two opinions rendered by the Federal Circuit in this case to date. Pet. App. 17a, 110a. Discovery is ongoing and there are unresolved issues of noninfringement (Pet. App. 92a, 98a, 101a) and invalidity (Pet. App. 109a) that have to be resolved at the District Court before respondents can be found liable for infringement of Petitioner's patent. Pet. App. 17a.

As with any patent litigation, the events that transpired before the patent issued can be as relevant as the current procedural posture in determining whether review is appropriate. This is particularly true where, as here, the sought-after review would only apply to a narrow set of facts that are unlikely to provide a

basis for a rule of law of general applicability. When the application for the patent-in-suit was undergoing examination at the Patent & Trademark Office ("PTO"), the patent applicants made several narrowing amendments to the claim at issue here in response to a rejection under, *inter alia*, 35 U.S.C. § 112 and ¶ 2 and 35 U.S.C. § 102(b). *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1340 (Fed. Cir. 2007) (Pet. App. 6a).[1]

As discussed in more detail below, one of the amendments to the patent claim at issue added a narrowing limitation on the depth of threads on a device, specifically requiring that they extend "to a depth below the diameter of the rod." Pet. App. 7a. The products accused of infringement here have threads that terminate above the rod, (Pet. App. 7a), thus precluding literal infringement. Pet. App. 9a. Infringement can only lie if (1) the threads terminating above the rod are equivalent to threads extending below the rod and (2) the patentee is not estopped from asserting infringement under the doctrine of equivalents. *Id.* However, when the applicants made a narrowing amendment for purposes of patentability, they created a presumption of prosecution history estoppel foreclosing reliance on the doctrine of equivalents for the amended claim elements when the patent eventually issued. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997) (stating that a presumption of prosecution history estoppel arises from amendments made to a patent claim during prosecution for

1. References to the decision below will heretofore be made to the appropriate page in Petitioner's Appendix.

"a substantial reason related to patentability."). This presumption may be rebutted if the rationale underlying the amendment bears "no more than a tangential relation" to the accused equivalent, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002) ("*Festo VIII*").

Here, the rationale underlying the amendment was "to capture the manner in which the stabilizer aspect of the invention operated and thereby overcome the 35 U.S.C. § 112 rejections." Pet. App. 12a. The Court of Appeals correctly decided that the rationale underlying the amendment could not be tangential to the accused equivalent. *Id.* The Court of Appeals then ruled correctly that the Petitioner is estopped from reliance upon the doctrine of equivalents. Pet. App. 14a.

I. HISTORY OF U.S. PATENT NO. 5,574,555

The patent-in-suit, U.S. Patent No. 5,474,555 ("the '555 patent"), issued from a continuation application of a previous ("parent") patent. *Cross Med. Prods. Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 (Fed. Cir. Dec. 12, 2005), Non-Confidential Joint Appendix.[2] A0182. The claims filed originally with the PTO, as well as the figures in both the parent and continuation applications, all included a cap between a nut and the rod. Pet. at 4; A2284-87. The length of the threads did not have to be specified, because of the intervening cap. Pet. at 5. During prosecution of the '555 patent application, the applicants added new claims without the cap limitation. *Id.*; A2314-18.

---

2. Subsequent references to this joint appendix will be identified only by "A."

When the claim that ultimately issued as claim 5 was first added, it specified "first threads" without any further details or limitations on these threads. A2316. This claim was deemed unpatentable by the patent examiner and rejected for numerous reasons, including, *inter alia*, inadequate written description, indefiniteness, and anticipation. A2324-28. The examiner rejected the claim as indefinite under 35 U.S.C. § 112 ¶ 2, because "[s]aid anchor seat portions" of the claimed device had no positive antecedent basis." A2325. The examiner also rejected the claim under 35 U.S.C. § 112 ¶ 1 for failing to provide an adequate written description of the invention, because certain limitations of the claim "fail[ed] to have support in the specification." A2327. The examiner rejected claim 5 further under 35 U.S.C. § 102(b) "as being clearly anticipated by Puno et al '602," referring to U.S. Patent No. 4,805,602. A2328. Finally, the examiner rejected the claim for obviousness type double patenting over the parent, U.S. Patent No. 5,360,431. Pet. App. 6a.

It was not just the claims that were deemed deficient by the examiner; he also found that the patent specification "fail[ed] to provide an enabling description of the embodiment of the action device excluding the cap/cap means. . . ." A2327. In order to persuade the PTO that the claim at issue was patentable, the applicants had to (1) amend the specification by adding a description enabling what was claimed, and (2) amend the claim to particularly point out and distinctly claim the subject matter of their invention. They did so by, *inter alia*, specifying how far the first threads extend in the claimed apparatus. Pet. App. 12a.

The examiner and the applicants then agreed, in a telephone interview, that, *inter alia*, the claims had to be amended "to reflect the above (i.e., the nut having a constant diameter bore and the external threads extending beyond the diameter of the rod)." A2332. The resulting amendment added the following limitation to the claimed first threads:

> . . . said seat means including a vertical axis and first threads *which extend in the direction of said vertical* axis *toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel* . . .

A2337 (emphasis added). In their remarks accompanying the amendment, the applicants stated unambiguously that:

> In response to the rejection under 35 U.S.C. §112 of the specification as well as the claims, the specification has been amended to recite the invention specifically shown in Figures 2 and 4. Accordingly, the claims have also been amended to define the anchor seat means having a channel *and threads which cooperate with the securing means* [i.e., the nut] so as to capture the stabilizer [i.e., rod] between the channel and the securing means since *the ancor* [sic] *seat threads extend toward the channel to a depth below the top of the stabilizer when it is in the channel.*

A2338 (emphasis added). These amendments are evidence that the claimed invention worked, in the

applicants' own words, "since" the anchor seat threads extend to a depth below the top of the stabilizer rod, thus allowing the threads to cooperate with the securing means (i.e., the nut to be screwed down upon the threads) to capture the stabilizer. Although the prosecution history is devoid of any explanation as to how the claim amendments overcame the examiner's additional objection under § 102(b), the patent examiner allowed the amended claim to issue. A2340.

By specifying that the threads extend "below the top of the stabilizer," the applicants narrowed their claim. The Federal Circuit held that "the thread depth limitation was added to capture the manner in which the stabilizer aspect of the invention operated and thereby overcome the 35 U.S.C. § 112 rejections." Pet. App. 12a. The accused equivalent had threads that stopped at the *top* of the stabilizer, and thus did not include the limitation added in the amendment—the very limitation that made the claim patentable. The Federal Circuit decided, on the basis of the undisputed facts of the case as laid out in the prosecution history of the '555 patent, that the amendment adding this limitation could not be tangential to the accused equivalent. *Id.* (stating that the accused equivalent "does *not* include threads extending 'to a depth below the top of the stabilizer' and correspondingly does *not* capture this aspect of the invention.") (emphasis in original). The Federal Circuit ruled correctly that the plaintiff failed to meet its burden and rebut the presumption of prosecution history estoppel, and is therefore estopped from asserting infringement under the doctrine of equivalents. *Id.*

REASONS FOR DENYING THE PETITION

Respondents Medtronic Sofamor Danek, Inc., and Medtronic Sofamor Danek USA, Inc., respectfully request that this Court deny Cross's petition for a writ of certiorari for the following reasons:

First, the case currently stands in an interlocutory posture because the Court of Appeals remanded the case for continued proceedings at the District Court, and Petitioner has not shown any exceptional or compelling reason for this court to depart from its ordinary practices and entertain this petition while issues remain unresolved below.

Second, the question presented by the petition is so vague and unbounded that it does not provide the proper notice to respondents or aid this court in framing the dispute, and does not meet the requirements of Supreme Court Rule 14.1(a) in that it is argumentative and not presented "in relation to the circumstances of the case."

Third, this case presents no new question of law for consideration by this Court because it is an intensely factbound application of the properly stated law of this Court and the Federal Circuit to the particular facts of this case.

Fourth, the Federal Circuit applied the established law correctly.

Fifth, this case presents no conflict, whether among circuits, within the Federal Circuit, or with this Court.

Sixth, this case presents no action by the Federal Circuit, such as formulation of a new "test" for estoppel, that is in opposition to any judgment by this Court.

A. The Interlocutory Posture of This Case Makes Review Inappropriate.

This case is currently pending in the District Court for the Central District of California. Pet. App. 112a. In this case, the District Court was instructed by the Federal Circuit to conduct further proceedings on Petitioner's claims of infringement and respondents' affirmative defenses and counterclaims of invalidity consistent with the two opinions rendered by the Federal Circuit in this case to date. Pet. App. 17a, 110a. Discovery is ongoing and there are unresolved dispositive issues of infringement (Pet. App. 92a, 98a, 101a) and validity (Pet. App. 109a) that must be resolved below before respondents can be found liable. Pet. App. 17a.

Any decision on this petition will not resolve this case because there are three remanded infringement issues that are particularly relevant to the non-infringement ruling that Petitioner seeks to have reviewed here. When the Federal Circuit ruled on the first appeal in this case (which is not the subject of this petition), it reversed *three* of the District Court's determinations on summary judgment: first, that the claim limitation of "operatively joined" was met by Medtronic's accused products, Pet. App. 92a; second, that the claim limitation of "securing means" was met by Medtronic's accused products, Pet. App. 98a; and third, that the claim limitation of "bear against said channel" was met by Medtronic's accused products. Pet. App. 101a. These

issues must be tried, in the first instance, in the District Court, and favorable resolution of any or all of them will result in a finding of non-infringement regardless of this Court's decision on this petition. Finally, even if infringement is found, the patent claim could be found invalid as obvious, (Pet. App. 106a - 109a), precluding Medtronic from liability for infringement. *See* 35 U.S.C. § 282.

Ordinarily, this Court will not grant review in the interlocutory posture of this case. *Bhd. of Locomotive Firemen & Enginemen v. Bangor & Aroostook R.R. Co.*, 389 U.S. 327, 328 (1967) ("[B]ecause the Court of Appeals remanded this case, it is not yet ripe for review by this Court.") (citing *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 257-58 (1916) ("The decree that was sought to be reviewed by certiorari at complainant's instance was not a final one, a fact that of itself alone furnished sufficient ground for the denial of the application . . .")). *See also Va. Military Inst. v. United States*, 508 U.S. 946, 946 (1993) (Scalia, J., concurring) ("We generally await final judgment in the lower courts before exercising our certiorari jurisdiction."). There is no special or compelling reason for this Court to depart from its ordinary course and exercise review here.

B. The Question Presented By Petitioner Does Not Satisfy The Requirements of This Court's Rule 14.1(a)

This Court's Rule 14.1(a) requires that the question presented is "expressed concisely in relation to the circumstances of the case," and not "argumentative or repetitive." There are two reasons for this rule. First,

"it provides the respondent with notice of the grounds upon which the Petitioner is seeking certiorari, and enables the respondent to sharpen the arguments as to why certiorari should not be granted." *Yee v. City of Escondido*, 503 U.S. 519, 535-36 (1992). Second, it "assists the court in selecting the cases in which certiorari will be granted," by identifying the specific "particularly important questions" and thus "enabl[ing] the Court to use its resources efficiently." *Id.*

Petitioner's "Question Presented," "[s]hould the Federal Circuit's material alteration of this Court's important precedent be permitted?" is argumentative in its erroneous assumption that the Federal Circuit has "materially altered" this Court's legal precedent. In so doing, Petitioner attempts to elevate the Federal Circuit's straightforward application of the law to the very particular facts of this case, to a question of national significance that is not supported on these facts.

The Petitioner's question also disregards the additional requirement of Rule 14.1(a) that the question be presented "in relation to the circumstances of the case." This case presents the specific question of whether the presumption of prosecution history estoppel is rebutted for a specific alleged equivalent to a patent claim limitation that was added in response to a rejection under § 112 and other statutory provisions. Petitioner's question glosses over this narrow context of the decision below and ignores the direct dependence of the outcome on the particular facts in the prosecution history of the patent in suit, and the specific accused equivalent. By ignoring the factual foundation on which any decision in this area is built, Petitioner's question is of no aid in framing the dispute.

As presented, this question would not serve the purpose of delineating the scope of the briefing and argument, in the event of plenary review. That lack of guidance would "thwart" the "integrity of the process of certiorari." *See Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992). The inadequate question presented by Petitioner is a sufficient reason, in and of itself, to deny certiorari.

C. Determination Of The Scope Of Estoppel Under The Doctrine Of Equivalents Is An Intensely Factbound Application Of The Law To The Particular Facts Of Each Case And The Decision Below Presents No Clear-Cut Question Of Law For Consideration By This Court.

Whether prosecution history estoppel applies to a particular claim element and an accused equivalent structure is a question of law that is heavily dependent upon the specific facts of each case. *Warner-Jenkinson*, 520 U.S. at 39 ("[U]*nder the particular facts of a case*, if prosecution history estoppel would apply . . . partial or complete judgment should be rendered by the court ") (emphasis added). Facts affecting the scope of estoppel include: what was specifically surrendered by the applicant during prosecution; what was given up by the applicant during argument in the PTO during prosecution; and, if the claims were amended in response to a prior art rejection, the prior art. *See, e.g., Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1462 (Fed Cir. 1998).

In addition to the prosecution history, the nature of the alleged equivalent must be analyzed because estoppel

is not evaluated in a vacuum, but rather in the context of the accused equivalent. This analysis is akin to the analysis of infringement under the doctrine of equivalents itself, in which

> [a]n analysis of the role played by *each element* in the context of *the specific patent claim* will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.

Warner-Jenkinson, 520 U.S. at 40 (emphasis added). Thus, in determining whether estoppel applies to a particular accused equivalent, the prosecution history, the specific patent claim, and the accused equivalent must all be analyzed in a detailed fact-specific inquiry.

The petition itself, replete with many, but not all, of the facts necessary to understand this case, demonstrates the factual dependence of findings in this area. The petition describes the transactions between applicant and PTO that resulted in the patent, Pet. at 4-5.; the nature of the specific accused equivalent device, Pet. at 6-8, and the factual foundation for the Federal Circuit's decision, Pet. at 9. Not only this case, but every case involving the determination of the scope of prosecution history estoppel, is intensely fact-bound. While every case is, of course, dependent upon the facts, the almost entirely factual nature of this analysis precludes this case from having the national importance justifying review by this court. *See United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

D. The Federal Circuit Faithfully Applied This Court's and the Federal Circuit's Law To These Facts When Deciding That Plaintiff Failed to Rebut the Presumption of Prosecution History Estoppel.

The decision below was faithful to both this Court's precedent and Federal Circuit law founded on that precedent. The Federal Circuit applied the principles set forth by this court in *Warner-Jenkinson* and *Festo VIII* when it determined the scope of the subject matter surrendered after determining that a narrowing amendment was made for a substantial reason relating to patentability. *Festo VIII* imposes the presumption that the patentee has surrendered all of the territory that lies between the original and amended claim limitations. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1367 (Fed. Cir. 2003) ("*Festo IX*") (citing *Festo VIII*, 535 U.S. at 740). *Festo VIII* further instructs that the patentee may rebut the presumption of surrender by demonstrating that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, i.e., was not directly relevant, was only slightly connected to, or was "merely touching" the equivalent in question. *See Festo IX*, 344 F.3d at 1369 (citing *Festo VIII*, 535 U.S. at 740, and two dictionaries).

The Federal Circuit correctly applied this precedent, in accord with *Festo IX*, in the instant case. The Federal Circuit first ascertained the facts, determining that the patent applicants made a narrowing amendment for "patentability"— i.e., to overcome the rejection on the basis of § 112 ¶ ¶ 1-2, and § 102(b). Pet. App. 6a. The appeals court then determined that the scope of the

surrendered subject matter encompassed the accused equivalent. Pet. App. 12a. Next, the court below determined the rationale for the narrowing amendment, finding that "the thread depth limitation was added to capture the manner in which the stabilizer aspect of the invention operated and thereby overcome the 35 U.S.C. § 112 rejections." *Id.* Finally, the Federal Circuit applied the law to these facts and concluded, as a matter of law, that this rationale was not tangential to the accused equivalent because the accused equivalent "does *not* include threads extending 'to a depth below the top of the stabilizer' and correspondingly does *not* capture," i.e., use, the very aspect of the invention that the applicants particularly and distinctly described in order to satisfy the statutory requirements for the claim.

The Federal Circuit's examination of the question of tangentialness in the instant case is an uncompromised application of the principles of estoppel, and rebuttal of the presumption of estoppel, laid down by this Court in *Festo VIII* and in *Warner-Jenkinson*. Although this Court did not define "tangential" in *Festo VIII*, the meaning of the word is implicit in the decision: certainly, an amendment is not tangential if it "does not surrender the particular equivalent in question," because "amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo VIII*, 535 U.S. at 740. Here, the Federal Circuit examined the question of disclaimed territory and concluded that the amendment was *central* to the issue of tangentiality because it *explicitly* excluded the thread depth of the accused equivalent from the claim.

The rationale stated by the applicants did not implicate prior art. They clearly stated that they added the thread depth claim limitation because that was what they thought they invented and how they had to claim it to satisfy the statutory requirements. Pet. App. 12a; A2338. Under the facts of this case, and following its own consistent interpretation of *Festo* and *Warner-Jenkinson*, the Federal Circuit made the correct decision here.

E. The Federal Circuit's Decision In This Case Is Consistent With Other Federal Circuit Decisions.

Comparison of this case with the other post-*Festo* decisions establishes that the Federal Circuit's holding in this case is consistent with other Federal Circuit decisions involving tangentialness.[3] Any differences in results arise because of different facts, as expected from

---

3. *See Amgen Inc. u Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1313-15 (Fed. Cir. 2006); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005); *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1299 (Fed. Cir. 2005); *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1385-86 (Fed. Cir. 2005); *Rhodia Chimie v. PPG Indus.*, 402 F.3d 1371, 1382-83 (Fed. Cir. 2005); *Bus. Objects, S.A. v. MicroStrategy, Inc.*, 393 F.3d 1366, 1374 (Fed. Cir. 2005); *Insituform v. CAT Contr., Inc.*, 385 F.3d 1360, 1368-71 (Fed. Cir. 2004); *Mycogen Plant Sci., Inc. v. Monsanto, Co.*, 91 Fed. Appx. 666, 669 (Fed. Cir. 2004) (nonprecedential); *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1357 (Fed. Cir. 2004); *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355, 1360 (Fed. Cir. 2003); *Okor v. Atari Games Corp.*, 76 Fed. Appx. 327, 332-33 (Fed. Cir. 2003) (nonprecedential); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1371-72 (Fed. Cir. 2003); *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003).

the intensely factual analysis required. The Federal Circuit's findings of both tangentiality and non-tangentiality, dependent upon the facts in each case, belies Petitioner's accusation that that court has "eviscerated" this Court's "tangential relation test." Pet. App. 15.

As an example of a Federal Circuit decision both internally consistent and consistent with this Court's *Festo VIII*, the appellate court ruled that the rationale for an amendment was not tangential in *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290 (Fed. Cir. 2005). In *Research Plastics*, the invention involved the placement of ribs on the interior surface of a caulking tube. *Id.* at 1292. During prosecution, the Examiner rejected the claims as obvious over a prior art patent claiming the use of ridges similar to the ribs in the patent-in-suit, but the prior art ridges were positioned near the nozzle end of the tube. *Id.* at 1293. In response to the rejection, the patentee amended the claims by adding the following language: "said ribs each occupying an area that is less than 0.5% of the area of said tube, and said ribs extending to said rear end of said hollow tube body." *Id.* (emphasis added). The patentee therefore disclaimed ribs positioned adjacent to the nozzle (opposite) end of the tube. *Id.* at 1298.

In *Research Plastics*, the accused equivalent had tubes with ribs located some distance from the rear edge of the tube's interior wall but still within the rear half of the tube and well away from the nozzle. *Id.* The Federal Circuit decided that the patentee could not expand the scope of its patent to cover the accused equivalent for the same reason set forth in this case: the patentee

amended its claims in response to a rejection for patentability purposes, disclaiming the very feature of the accused equivalent that it was now trying to cover. The Federal Circuit noted that "the alleged equivalent—ribs extending to a point short of the rear edge of the tube—is not tangential to the purpose of the amendment, because the purpose of the amendment was to avoid rejection based on rib placement." *Id.* at 1299.

Here, as the Federal Circuit recognized correctly, both the purpose of the amendment was to avoid rejection based on thread placement, and that rationale is not tangential to the thread placement in the accused devices. In both *Research Plastics* and *Cross*, the Federal Circuit correctly applied the facts of the case according to the principles laid down in *Festo VIII*.

The Federal Circuit has also found amendments to be tangential where the facts warrant such a finding. The court's approach in these cases further demonstrates its internal consistency, as well as its consistent adherence to the principles laid down in *Festo VIII*. For example, in *Insituform Techs., Inc. v. CAT Contr., Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), the claim in question covered a method of resin coating an absorbent tubular liner on the interior of, e.g., underground pipes. 385 F.3d. at 1362. The resin was introduced in bulk at one end of the tube and drawn into the tube by a vacuum applied downstream through a cup attached to a hole in the outer wall of the tube. *Id.* at 1363. As the resin reached the cup, the cup was moved to a point farther downstream. *Id.*

During prosecution, the *Insituform* applicant had to overcome a prior art rejection based on an invention that used a single vacuum source fixed at the far end of the

tube. *Id.* at 1370. The original claim did not limit the number of vacuum sources. 385 F.3d. at 1366. The applicant amended the claim to include a single movable cup. *Id.* On the basis of the applicant's explanation of the amendment in the prosecution history, the Federal Circuit found that the rationale for the amendment was to differentiate applicant's method of applying a vacuum at multiple points on the tube by using a cup movable along the length of the tube, from the prior art method of using a single vacuum source at the end of the tube. *Id.* at 1369. However, the accused equivalent was a multiple cup system that also applied the vacuum at multiple locations. *Id.* at 1370. The Federal Circuit concluded that the amendment was tangential to the accused equivalent, because it related to an entirely different aspect of the invention than that which was accused of equivalence. *See id.* In other words, "an amendment based on *where* the vacuum source was located was only tangentially related to an equivalent directed at the *number* of vacuum sources." Pet. App. 11a (reconciling *Insituform* with this case) (emphasis in original). *See also Insituform*, 385 F.3d at 1370.

The Federal Circuit applied the same tangentiality analysis in *Insituform* and in this case, and obtained different results because different facts applied. The Federal Circuit decided that the *Insituform* amendment was tangential because it related to a different aspect of the invention than that implicated in the accused equivalent: the rationale underlying the amendment concerned the *location* of the vacuum source, while the equivalence hinged on the *number* of vacuum sources. Here, in contrast to *Insituform*, the amendment was not tangential because it related to precisely the same aspect of the invention, the thread depth, that is implicated in the accused equivalent.

Pet. App. 12a. The same legal analysis that led the Federal Circuit to find tangentiality in *Insitufor* led to a finding of lack of tangentiality here because different facts mandated different results.

F. The Federal Circuit Has Neither "Eviscerated" The Tangential Relation Principle Nor Created A New Test.

The Federal Circuit's application of *Festo VIII* has hardly "eviscerated" the tangential relation principle, not withstanding Petitioner's melodramatic assertion to the contrary. The court has found amendments to be tangential in one-seventh (~14%) of the fourteen cases involving tangentialness that have come before the Federal Circuit since *Festo VIII*.[4] Plainly, the tangentialness test is not "virtually insurmountable," as Petitioner argues. Pet. at 19. The tangential rebuttal principle is narrow and will only rarely provide a basis on which the patentee can rebut the statutory presumption, *see* Pet. App. 18a, but it is only one of these ways in which a patentee may rebut a presumption that this Court has ruled should apply. The two decisions since *Festo VIII* in which an amendment has been found tangential show that the Federal Circuit has not "eviscerated" the principle, particularly in view of the burdens that must be surmounted and the relatively few numbers of cases in which this issue has arisen.

The appeals court correctly stated and applied the law to the particular facts of this case. It did not apply a "new test" or disregard the rationale for the amendments. To the contrary, it determined the rationale underlying the

4. *Instituform Tech., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006).

amendment from the applicants remarks. Pet. App. 12a. Having made that determination, the Federal Circuit correctly ruled that the rationale was not tangential to the alleged equivalent and Cross failed to rebut the presumption.

CONCLUSION

This petition should be denied not least because no question of law suitable for review by this Court has been presented. The Federal Circuit, following the teachings of this Court, decided correctly under the facts of this case that the rationale underlying plaintiff's amendment bore more than a tangential relation to the accused equivalent, so that plaintiff could not rebut the presumption and meet its burden of proving that the amendment was not tangential to the equivalent in question.

There is no infringement under the doctrine of equivalents under the specific facts of this case because of prosecution history estoppel, as the Federal Circuit ruled correctly.

Respectfully submitted,

DIRK D. THOMAS
Counsel of Record
ROBERT A. AUCHTER
JEFFREY I. FREY
DEWEY & LEBOEUF LLP
975 F Street, N.W.
Washington, D.C. 20004-1405
(202) 862-1000

October 9, 2007

Counsel for Respondents

71

FILED
OCT 23 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 07-186

In The Supreme Court of the United States

CROSS MEDICAL PRODUCTS, INC.,
PETITIONER,

V.

MEDTRONIC SOFAMOR DANEK, INC.
AND MEDTRONIC SOFAMOR DANEK USA, INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF OF PETITIONERS

J. SCOTT BALLENGER
Counsel of Record
LATHAM & WATKINS LLP
555 11TH STREET, N.W.
SUITE 1000
WASHINGTON, DC 20004
(202) 637-2200

BRUCE D. KUYPER
MARK A. FINKELSTEIN
MARK D. KACHNER
LATHAM & WATKINS LLP
650 TOWN CENTER DRIVE
20TH FLOOR
COSTA MESA, CA 92626
(714) 540-1235

TABLE OF CONTENTS

Page

TABLE OF CONTENTS.....i
TABLE OF AUTHORITIES..... ii
ARGUMENT.....1
CONCLUSION.....9

TABLE OF AUTHORITIES

Page(s)

CASES

Almota Farmers Elevator & Warehouse Co. v. United States,
409 U.S. 470 (1973) 8

Amgen, Inc. v. Hoechst Marion Roussel, Inc.,
457 F.3d 1293 (Fed. Cir. 2006),
cert. denied, 127 S. Ct. 2270 (2007) 7

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
535 U.S. 722 (2002) 1, 4

Graver Tank & Manufacturing Co. v. Linde Air Products Co.,
339 U.S. 605 (1950) 4

Insituform Technologies, Inc. v. Cat Contracting, Inc.,
385 F.3d 1360 (Fed. Cir. 2004) 7

Primos, Inc. v. Hunter's Specialties, Inc.,
451 F.3d 841 (Fed. Cir. 2006) 7

Research Plastics, Inc. v. Federal Packaging Corp.,
421 F.3d 1290 (Fed. Cir. 2005) 5, 6

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17 (1997) 4

STATUTORY AUTHORITY

35 U.S.C. § 112 2

OTHER AUTHORITY

Robert L. Stern et al., *Supreme Court Practice*
§ 4.18 (8th ed. 2002) 9

ARGUMENT

The Federal Circuit's articulation and application of the standard for rebutting prosecution history estoppel is deeply flawed and inconsistent with this Court's precedents. Respondents correctly note that petitioner amended claim 5 of the '555 Patent to add a thread depth limitation—and protest that their own product uses threads that are not as long as the claim recites. Standing alone, however, that proves only that respondents' product does not literally infringe that claim. It does not speak to whether there is infringement under the doctrine of equivalents. Like the Federal Circuit, respondents attempt to obfuscate the *reason* that petitioner added a thread depth limitation, which was merely to explain more fully one way that the invention could be "enabled" (i.e., made to work). Petitioners could have specified any number of other ways the nut could have been tightened against the rod, including the inconsequential variation that respondents have used.

Under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the *rationale* underlying this amendment thus bears no more than a tangential relationship to the "equivalent" respondents have employed. The Federal Circuit acknowledged that the reason for this amendment was merely to enable the invention, but then wholly ignored that reason and focused instead on the *result* of the amendment (i.e., its subject matter) when holding that prosecution history estoppel applies here. The Federal Circuit's recent decisions have consistently ignored that crucial distinction, with the consequence that prosecution history estoppel has essentially swallowed the doctrine of equivalents. This fundamental misstatement of the law must be corrected.

1. Respondents' opposition brief labors to make the Federal Circuit's statement of the law and subsequent analysis consistent with *Festo* by trying to create the impression that the *reason* for the disputed amendment was to disclaim subject matter related to thread depth. But the

Federal Circuit agreed that the Patent Examiner's objection that led to the disputed amendment was based on the enablement requirement. *See* 35 U.S.C. § 112; Pet. App. 7a. The Examiner did not require the patentee to disclaim subject matter that lacked threads that extend "to a depth below the diameter of the rod," in order for the invention to be patentable. Requiring that the threads extend below the diameter of the rod was just one way the patentee was able to demonstrate that the nut would make direct contact with the rod, thus stabilizing the rod without the use of a cap. In other words, the purpose of the amendment was to overcome the enablement rejection by demonstrating one way in which the device could work. But the patentee had other options to overcome the same enablement rejection—including the trivial variation that respondents employed here in a transparent effort to circumvent claim 5 of the '555 Patent. Under these circumstances there is no reason for prosecution history estoppel to displace the doctrine of equivalents.

Respondents, like the Federal Circuit, contend that "this rationale was not tangential to the accused equivalent because the accused equivalent 'does *not* include threads extending "to a depth below the top of the stabilizer" and correspondingly does *not* capture'" the subject matter disclaimed by the patentee. *See* Brief in Opposition at 15 (quoting Pet. App. 12a). Again, however, that is just a long way of saying that respondents' device is not literally within the claims, as amended. That analysis fails to engage at all with the *reason* for the amendment, and instead applies prosecution history estoppel whenever the *subject matter* of the amendment bears a more than tangential relationship to the accused equivalent. The consequence is that a crafty infringer can always look back to some amendment that was made by the patent owner, and then make a trivial modification to his product that implicates that amendment.

By focusing on the *rationale underlying the amendment*, this Court recognized in *Festo* that the patent prosecution process frequently requires patentees to amend claim

limitations for numerous reasons, and that the particulars of the amendment process, rather than the subject matters touched by that process, define the scope of prosecution history estoppel. As the petition explained, if the patentee amends his patent claims on a box to specify that it be held together with glue, a product held together with rubber cement may still infringe under the doctrine of equivalents. Prosecution history estoppel is appropriate if the *reason* for the amendment was to avoid prior art involving rubber cement, or an objection by the examiner that a box held together with rubber cement is too obvious to be patented. But prosecution history estoppel *is not* appropriate if the amendment was to avoid prior art involving boxes that could be disassembled, or (as here) simply an objection that the invention was not fully enough described to allow a competent person to build it.

The Federal Circuit's reformulation of the test in this and other recent cases completely abandons those critical distinctions, and treats the rationale of the amendment as irrelevant so long as its subject matter encompasses the accused equivalent. This test contravenes *Festo* and upsets the balance this Court carefully crafted between prosecution history estoppel and the doctrine of equivalents. The Federal Circuit's analysis unfairly excludes subject matter that should be protected to give effect to the doctrine of equivalents and to this Court's recognition that a patent extends beyond the claim's literal terms to protect inconsequential variation. In light of the Federal Circuit's new legal standard for the tangential relation test, prosecution history estoppel is now essentially an insurmountable bar. Thus, the Federal Circuit has essentially resurrected the pre-*Festo* "complete bar" against the doctrine of equivalents upon claim amendment. This critical error should be corrected.

2. The Federal Circuit has not merely misapplied a correctly stated legal principle to the facts of this case, as respondents argue.

Petitioner does not dispute the Federal Circuit's application of law to facts, but its profoundly important reframing of the basic legal issue. This Court's tangential relation test asks whether the equivalent in question bears no more than a tangential relationship to the reason for the amendment. The Federal Circuit, however, has reformulated the test to instead ask whether "the accused equivalent ... *relates to the amendment.*" Pet. App. 12a (emphasis added). This flawed statement of the law is a direct result of the Federal Circuit's fundamentally incorrect understanding of the "tangential relation" test for rebutting the presumption of prosecution history estoppel.

Of course respondents are correct that the standard for rebutting a presumption of prosecution history estoppel, when properly understood, is a fact-intensive inquiry in any particular case. But that does not counsel against review by this Court to correct the Federal Circuit's misunderstanding (and mis-articulation) of the governing legal standard. A lower court's primary function is to apply legal standards to complex facts, and this frequently requires fact-intensive inquiries. Review remains appropriate where a lower court misstates the law in a manner that rises to national importance.

The legal question involved here is of national importance because it goes to the core of the delicate balance this Court has achieved between prosecution history estoppel and the doctrine of equivalents. *See Festo Corp.*, 535 U.S. at 732 (noting that while "the doctrine of equivalents renders the scope of patents less certain," this is "the price of ensuring the appropriate incentives for innovation"); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) (confirming continued vitality of doctrine of equivalents); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) (doctrine of equivalents prevents conversion of patent protection into "a hollow and useless thing"). The importance of this legal issue is amplified because the Federal Circuit, unlike regional circuit

courts, creates binding precedent on every district court in the country. This Court is the only judicial body with the ability to rein in the Federal Circuit when it evidences an intent to abandon this Court's precedents. *See, e.g.*, Pet. App. 17a-22a (Rader, J., concurring).

3. Respondents contend that the Federal Circuit's enunciation of the law in this case is consistent with its statement of the law in prior Federal Circuit cases. To a substantial extent they are correct—which just further highlights that this is not a one-time aberration or misapplication of properly stated rules. This case is one of several recent cases in which the Federal Circuit has decisively broken from the correct approach to prosecution history estoppel (focusing on the reason for an amendment) in favor of a new analysis (focusing on the subject matter of an amendment) that is entirely inconsistent with *Festo*.

Respondents identify *Research Plastics, Inc. v. Federal Packaging Corp.*, 421 F.3d 1290 (Fed. Cir. 2005), as an example of the Federal Circuit's "proper" articulation of the legal standard and subsequent "proper" application of that law to the facts of the case. In *Research Plastics*, the Federal Circuit actually misstated the test in a manner similar to its error here. That error was, however, harmless in *Research Plastics* because on the facts of that case both the result of the amendment and the rationale underlying the amendment supported estoppel, and the Federal Circuit was not called upon to distinguish between these important concepts.

In *Research Plastics*, the patent at issue and accused equivalent related to rib placement on the interior surface of caulking tubes. 421 F.3d at 1292. The Federal Circuit first determined that an amendment was made during prosecution to overcome a prior art rejection related to rib placement. The Court next considered that the accused equivalent contained ribs placed in a location that had been disclaimed by the amendment. It concluded that prosecution history estoppel applied and had not been rebutted, because "the alleged equivalent—ribs extending to a point short of the

rear edge of the tube—is not tangential to the purpose of the amendment, because the purpose of the amendment was to avoid rejection based on rib placement." *Id.* at 1299.

As in this case, the Federal Circuit grossly oversimplified the issue in *Research Plastics*. The articulation quoted above contains a subtle reformulation of the test for rebutting prosecution history estoppel, when contrasted with the test as laid down by this Court in *Festo*. In a superficial sense it will *always* be true that the "purpose" of an amendment is "to avoid rejection based on" the prior absence of that amendment. But the point of *Festo* is that some grounds for rejection, and hence reasons for amendment, support later prosecution history estoppel and some do not. The Federal Circuit has transitioned to a standard that ignores the *rationale* behind the amendment. Its claim in *Research Plastics* that "the purpose of the amendment was to avoid rejection based on rib placement" is just another way of saying that during prosecution the patent owner was forced to add a specification about rib placement—i.e., that the subject matter of the amendment related to the placement of ribs in the tube. A genuine inquiry into the purpose of the amendment would have asked why the patent owner had to add the rib specification. If the answer had been to avoid an enablement rejection (as here) then that purpose might have been only tangential to the accused equivalent. As it happened, the purpose of the amendment was to avoid rejection on the ground that without the new rib placement the claimed invention was obvious in light of prior art. Given that purpose, prosecution history estoppel would be appropriate whenever an alleged equivalent related to rib placement—and the Federal Circuit's oversimplification of the legal issue was effectively harmless error.

The Federal Circuit's legal error manifests itself where the rationale for the amendment does not support estoppel even though the *result* of the amendment bears a more than tangential relation to the equivalent in question. As discussed *supra*, the purpose of the amendment in this case

was distinct from the result of the amendment. The purpose of the amendment was to satisfy the enablement requirement. As one way of satisfying this rejection, the patentee chose to amend the claim by specifying thread depth. But this did not surrender every other equivalent way of satisfying the enablement rejection, any more than equivalents would have been surrendered had the thread depth language been included in the original claim, before amendment. The Federal Circuit's conflation of purpose with result, here and in *Research Plastics*, prevents it from recognizing that distinction.

As the petition pointed out, the Federal Circuit also employed an incorrect legal standard in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2270 (2007). There too, the Federal Circuit ignored the rationale underlying the amendment in question and instead relied solely on the amendment's subject matter, which was compared to the accused equivalent. The amendment in question was to overcome a prior art rejection, where the art taught a non-naturally occurring protein, but did not specify the length of the amino acid sequence. *See id.* at 1314-15. The patentee chose amino acid length as the basis for distinguishing the invention over this cited art, rather than choosing from a number of other grounds which also could have successfully served as a basis of distinction. The Federal Circuit penalized Amgen for that choice, even though the length of the amino acid sequence was only indirectly related to the rationale underlying the patent amendment.

Respondents point to *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), and *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006), as the lone post-*Festo* examples where the Federal Circuit concluded that the rationale underlying an amendment bore no more than a tangential relation to the equivalent in question. In both cases, the patentee successfully rebutted the presumption of prosecution history

estoppel. But these past decisions have been supplanted by more recent opinions such as this case and *Amgen*, which eviscerate the "tangential relation" test by focusing only on the subject matter of an amendment and ignoring its purpose. Indeed, in this case Judge Rader noted his belief that *Insituform* and *Primos* could easily have come out the other way—which is certainly true in light of the court's new understanding of the law. *See* Pet. App. 19a (Rader, J., concurring). If cases similar to *Insituform* and *Primos* arose tomorrow, the Federal Circuit's reasoning in this case and in *Amgen* would lead it to hold that the tangential relation test has not been satisfied.

4. Respondents accuse the petition's Question Presented of being too argumentative, but the substance of their objection is simply that they disagree with petitioner's portrayal of the scope and basis of the Federal Circuit's decision. This is a sideshow. The Question Presented and petition obviously made the substance of the dispute here clear to respondents. Their opposition brief squarely addresses whether the Federal Circuit materially altered this Court's established "tangential relation" test for rebutting the presumption of prosecution history estoppel—the issue posed in the Question Presented in the petition. The respondents also exercised the option to rephrase the Question Presented to identify what *they* perceive the issue to be, *see Almota Farmers Elevator & Warehouse Co. v. United States*, 409 U.S. 470, 473 & n.1 (1973), in a manner suggesting disagreement with petitioner's substantive argument but also recognition of the question raised. If this Court would prefer that briefing proceed under a different formulation of the question, it may of course adopt its own phrasing in the order granting certiorari.

5. Respondents incorrectly contend that the interlocutory posture of this case makes review inappropriate. The Federal Circuit's decision precludes infringement of the asserted claims of the '555 Patent based on Medtronic's redesigned screws, even though the case was remanded for

further factual findings on infringement theories against other Medtronic products. The interlocutory posture is no reason to defer review. An interlocutory posture is "no impediment to certiorari where the opinion of the court below has decided an important issue, otherwise worthy of review, and Supreme Court intervention may . . . hasten or finally resolve the litigation." Robert L. Stern et al., *Supreme Court Practice* § 4.18 (8th ed. 2002). The legal question presented in this petition turns on the proper interpretation of this Court's precedent. The balance between prosecution history estoppel and the doctrine of equivalents depends on this Court correcting the Federal Circuit's efforts to skew that balance.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

J. SCOTT BALLENGER
Counsel of Record
LATHAM & WATKINS LLP
555 11TH STREET, N.W.
SUITE 1000
WASHINGTON, DC 20004
(202) 637-2200

BRUCE D. KUYPER
MARK A. FINKELSTEIN
MARK D. KACHNER
LATHAM & WATKINS LLP
650 TOWN CENTER DRIVE
20TH FLOOR
COSTA MESA, CA 92626
(714) 540-1235